

US3742384 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:14:07

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US3742384

Form: Participant Creation

Generated On: 26 Nov 2020 11:14:07

[Participant ID](#)

US3742384

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

US3742384

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:14:07

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

US3742384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:07

Date of Birth (MMM yyyy)	(b) (6) 1980
Age	40
Age Units	YEARS
Age (Derived)	40
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	True
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

US3742384

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:07

Date of Informed Consent (<i>dd MMM yyyy</i>)	16 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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

US3742384

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:14:07

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3742384

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:14:07

Were any significant conditions reported?

Yes ☒

No ☐

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:14:07

Condition	HYPERTENSION
Start date (dd MMM yyyy)	30 JUN 2017
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)	JUN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:14:07

Condition	SARCOIDOSIS
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	16 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	08:18 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 08:18
Height (<i>xxx.x</i>)	64.5 in
Weight (<i>xxx.x</i>)	241.0 lb
BMI (<i>xxx.x</i>)	40.81384 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3742384

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3742384

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:14:07

Date of assessment (*dd MMM yyyy*) 16 SEP 2020

Is the participant of childbearing potential? Yes ☒ No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

US3742384

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	16 SEP 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

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

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	True
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

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

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

US3742384

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:14:07

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:07

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

What was the participant's randomization number? 190964

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 ☒

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:14:07

Height	ND - Not Done
Weight	ND - Not Done

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	08:18 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 08:18
Temperature (xxx.x)	098.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	092 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	086 mmHg
Diastolic Blood Pressure units	MMHG

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	10:23 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 10:23
Temperature (xxx.x)	99.2 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	096 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	085 mmHg
Diastolic Blood Pressure units	MMHG

US3742384

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3742384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed _____ Urine ☐

Serum ☐

Result _____ Positive ☐

Negative ☐

Was FSH sample collected? Yes ☐

No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

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 SEP 2020

What was the treatment time? (00:00-23:59) 09:53 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 09:53

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

US3742384

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:07

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	16 SEP 2020
Collection time (<i>00:00-23:59</i>)	08:44 (24 HR)
Collection date and time (derived)	16 SEP 2020 08:44

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:14:07

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:47	16 SEP 2020 08:47
Nasopharyngeal Swab 2	No		

US3742384

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 10:23

PC Open Date & Time

16 SEP 2020 10:13

PC Close Date & Time

16 SEP 2020 12:43

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °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	17 SEP 2020 01:49
PC Open Date & Time	16 SEP 2020 13:38
PC Close Date & Time	17 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:07

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

98.2 °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

17 SEP 2020 17:27

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:07

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 09:14

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 17:43

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

20 SEP 2020 20:45

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

21 SEP 2020 17:31

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

22 SEP 2020 17:04

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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 SEP 2020 10:25

PC Open Date & Time

16 SEP 2020 10:13

PC Close Date & Time

16 SEP 2020 12:43

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 01:47

PC Open Date & Time

16 SEP 2020 13:38

PC Close Date & Time

17 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:07

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 SEP 2020 17:28

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:07

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

19 SEP 2020 09:15

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 17:44

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 20:46

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 17:31

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 17:05

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 10:27
PC Open Date & Time	16 SEP 2020 10:13
PC Close Date & Time	16 SEP 2020 12:43

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 01:48
PC Open Date & Time	16 SEP 2020 13:38
PC Close Date & Time	17 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

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 ☒

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

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

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

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 ☒

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

Yes ☐	
PC Time stamp	19 SEP 2020 09:15
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

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 ☒

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

Yes ☐	
PC Time stamp	19 SEP 2020 17:44
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

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 ☒

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

Yes ☐	
PC Time stamp	20 SEP 2020 20:46
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

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 ☒

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

Yes ☐	
PC Time stamp	21 SEP 2020 17:32
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

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 ☒

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

Yes ☐	
PC Time stamp	22 SEP 2020 17:05
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3742384

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742384

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742384

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742384

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:07

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	07:30 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 07:30
Temperature (xxx.x)	100.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	108 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	080 mmHg
Diastolic Blood Pressure units	MMHG

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	08:51 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 08:51
Temperature (xxx.x)	99.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	115 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	072 mmHg
Diastolic Blood Pressure units	MMHG

US3742384

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3742384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	13 OCT 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

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)	13 OCT 2020
What was the treatment time? (00:00-23:59)	08:19 (24 HR)
Treatment Date and Time (derived)	13 OCT 2020 08:19
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

US3742384

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:07

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	13 OCT 2020
Collection time (<i>00:00-23:59</i>)	07:59 (24 HR)
Collection date and time (derived)	13 OCT 2020 07:59

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:14:07

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:57	13 OCT 2020 07:57
Nasopharyngeal Swab 2	No		

US3742384

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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 99.2 °F

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

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

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

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

PC Time Stamp 13 OCT 2020 09:00

PC Open Date & Time 13 OCT 2020 08:39

PC Close Date & Time 13 OCT 2020 11:09

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

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

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

PC Time Stamp 14 OCT 2020 08:44

PC Open Date & Time 13 OCT 2020 12:04

PC Close Date & Time 14 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:07

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

97.9 °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

15 OCT 2020 07:14

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:07

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 15:57

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 19:21

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:07

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

99.1 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

17 OCT 2020 18:46

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp 18 OCT 2020 19:01

PC Open Date & Time 18 OCT 2020 12:00

PC Close Date & Time 19 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

19 OCT 2020 20:44

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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

13 OCT 2020 09:00

PC Open Date & Time

13 OCT 2020 08:39

PC Close Date & Time

13 OCT 2020 11:09

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 08:44

PC Open Date & Time

13 OCT 2020 12:04

PC Close Date & Time

14 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:07

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 OCT 2020 09:46

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:07

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

15 OCT 2020 15:57

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:07

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

16 OCT 2020 19:22

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:07

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

17 OCT 2020 18:46

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:07

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

18 OCT 2020 19:02

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:07

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

19 OCT 2020 20:45

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 09:01
PC Open Date & Time	13 OCT 2020 08:39
PC Close Date & Time	13 OCT 2020 11:09

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 08:44
PC Open Date & Time	13 OCT 2020 12:04
PC Close Date & Time	14 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

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 ☒

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

Yes ☐	
PC Time stamp	15 OCT 2020 09:47
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

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 ☒

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

Yes ☐	
PC Time stamp	15 OCT 2020 15:57
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

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 ☒

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

Yes ☐	
PC Time stamp	16 OCT 2020 19:22
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

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 ☒

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

Yes ☐	
PC Time stamp	17 OCT 2020 18:47
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

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 ☒

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

Yes ☐	
PC Time stamp	18 OCT 2020 19:02
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

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 ☒

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

Yes ☐	
PC Time stamp	19 OCT 2020 20:45
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 20 OCT 2020 12:19

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 20 OCT 2020 12:19

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	20 OCT 2020 12:19
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3742384

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742384

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742384

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742384

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:07

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3742384

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

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

US3742384

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:07

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.

US3742384

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:07

Was the sample collected?	Yes ☐
	No ☐
Collection date (<i>dd MMM yyyy</i>)	
Collection time (<i>00:00-23:59</i>)	
Collection date and time (derived)	

US3742384

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this 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	16 NOV 2020 08:40:34
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 15:10:27
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

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02 NOV 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

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05 NOV 2021 00:01

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09 NOV 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

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16 NOV 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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14 DEC 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

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03 MAY 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

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17 MAY 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

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07 JUN 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

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14 JUN 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

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21 JUN 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

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26 JUL 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

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02 AUG 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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16 AUG 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

DAY 705

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

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23 AUG 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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30 AUG 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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20 SEP 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3742384

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:14:07

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3742384

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:14:07

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

AEID	
Adverse event	BACTERIAL VAGINOSIS
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)	7 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	15 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

334 of 1935

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

AEID	
Adverse event	HEADACHE
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)	13 OCT 2020
Start time (00:00-23:59)	05:00 (24 HR)
AE start date and time (derived)	13 OCT 2020 05:00
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	13 OCT 2020
End time (00:00-23:59)	08:00 (24 HR)
AE End Date and Time (derived)	13 OCT 2020 08:00
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	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	336 of 1935

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

AEID	USA-US127-2020-MRNA-1273-P30 1000008
Adverse event	DIVERTICULITIS
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)	01 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	01 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	09 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	338 of 1935

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☒ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	VOLUNTEER REPORTS BEING HOSPITALIZED FOR DIVERTICULITIS. SAE REPORTED.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:14:07

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

Yes ☒

No ☐

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

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

Name of Medication	CHANTIX
Prophylaxis	Yes ☐ No ☒
Indication	SMOKING CESSATION
Dose per administration	1
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 ☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

	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)		12 DEC 2016
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

Name of Medication	HYDROCHLOROTHIAZIDE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	12.5
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 ☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

	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)		30 JUN 2017
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	☒

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

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

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

	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)		30 JUN 2017
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	☒

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

Name of Medication	PREDNISONE
Prophylaxis	Yes ☐ No ☒
Indication	SARCOIDOSIS
Dose per administration	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 ☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

	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 JUL 2019
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

Name of Medication	TRELEGY ELLIPTA
Prophylaxis	Yes ☐ No ☒
Indication	SARCOIDOSIS
Dose per administration	100-62.5
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 ☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

	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 2019
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	☒

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

Name of Medication	CHROMMATE
Prophylaxis	Yes ☒ No ☐
Indication	SUPPLEMENT PROPHYLAXIS
Dose per administration	1
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 ☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

	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 JAN 2018	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

Name of Medication	METRONIDAZOLE
Prophylaxis	Yes ☐ No ☒
Indication	BACTERIAL VAGINOSIS
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 ☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

	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)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		15 OCT 2020
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	☒

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

Name of Medication	B12 INJECTION
Prophylaxis	Yes ☐ No ☒
Indication	WEIGHT LOSS
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 ☒

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

	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)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☒
	804	☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

Name of Medication	LIPOTROPIC [METHIONINE/INOSITOL/CHOLINE]
Prophylaxis	Yes ☐ No ☒
Indication	WEIGHT LOSS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	INJECTION
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 ☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

	Intraocular	☐
	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

Name of Medication	BC TAB [ASPIRIN/CAFFEINE]
Prophylaxis	Yes ☐ No ☒
Indication	HEADACHE
Dose per administration	845/65
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 ☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

	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)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		13 OCT 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 ☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	HEADACHE
Dose per administration	400
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 ☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

	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)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		17 OCT 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 ☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

Name of Medication	LOVENOX
Prophylaxis	Yes ☒ No ☐
Indication	THROMBUS PROPHYLAXIS
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 ☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

	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)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

Name of Medication	KETOROLAC
Prophylaxis	Yes ☐ No ☒
Indication	DIVERTICULITIS
Dose per administration	30
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 ☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

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)	02 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

Name of Medication	PIPERACILLIN TAZOBACTAM
Prophylaxis	Yes ☐ No ☒
Indication	DIVERTICULITIS
Dose per administration	3.375
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 ☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

	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)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

Name of Medication	ONDANSEETRON
Prophylaxis	Yes ☐ No ☒
Indication	NAUSEA
Dose per administration	4
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

	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)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

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

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

	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)		02 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ☒ No ☐
Indication	INFLUENZA PROPHYLAXIS
Dose per administration	0.5
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 ☒

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

	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)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		28 OCT 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	☐

US3742384

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:14:07

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3742384

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:14:07

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

US3742384

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:14:07

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 ☐

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

SAEID	USA-US127-2020-MRNA-1273-P301000008
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	MD
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:14:07

SAEID	USA-US127-2020-MRNA-1273-P301000008
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	MD
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	04/NOV/2020 10:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:14:07

SAEID	USA-US127-2020-MRNA-1273-P301000008
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	MD
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	11/NOV/2020 22:18
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

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:14:07

SAEID	USA-US127-2020-MRNA-1273-P301000008
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	MD
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/NOV/2020 18:06
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

US3742384 (Prod: University of Maryland School of Medicine)

US3742384

Form: Participant Creation

Generated On: 26 Nov 2020 11:14:07

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3742384'	RWS_ENDPOINT ENDPOINT (b) (4) 	16 Sep 2020 11:34:18

US3742384

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:14:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 13:59:23

US3742384

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '16 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	16 Sep 2020 11:34:19

US3742384

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 13:59:23

US3742384

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:14:07

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	16 Sep 2020 13:59:23

US3742384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered (b) (6) 1980' reason for change: Data Entry Error	RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 14:59:36
User entered (b) (6) 1940'	RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 11:34:20

US3742384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:07

Age

Audit	User	Time (GMT)
User closed query 'Per CDM Re-query: Response is noted. Please confirm if deviation was reported. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 18:02:35
Query 'Per CDM Re-query: Response is noted. Please confirm if deviation was reported. ' answered with 'Deviation will be reported' (Site from DM).	Sherry McCammon (b) (4)	17 Nov 2020 19:39:26
User opened query 'Per CDM Re-query: Response is noted. Please confirm if deviation was reported. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:30:11
User closed query 'Age does not fit Cohort. Please review and update. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:29:28
Query 'Age does not fit Cohort. Please review and update. ' answered with 'Participant was randomized incorrectly. Made several data change requests but was informed that changes can not be make to stratification ' (Site from DM).	Kaitlin Mason (b) (4)	09 Nov 2020 18:01:09
User opened query 'Age does not fit Cohort. Please review and update. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:10:09
Query 'Age does not fit Cohort. Please review and update.' canceled (Site from System).	(b) (4), (b) (6)	05 Nov 2020 05:10:03
Comment added 'A DATA CHANGE REQUEST WAS SUBMITTED AND IT STATES IT WAS COMPLETED BUT THE COHORT HAS NOT CHANGED.'.	Sherry McCammon (b) (4)	24 Sep 2020 19:49:26
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	16 Sep 2020 14:59:36
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	16 Sep 2020 14:00:52
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	16 Sep 2020 13:59:42
User entered '40'	Hassan Haji (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:07

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:07

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '40'	System	16 Sep 2020 14:59:36
User entered '80'	System	16 Sep 2020 14:00:52

US3742384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:07

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:07

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:07

[White](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:07

[Black](#)

Audit	User	Time (GMT)
User entered '1'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:07

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:07

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:07

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:07

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:07

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:07

Unknown

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:07

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:00:52

US3742384

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	16 Sep 2020 14:00:52

US3742384

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '2020'	System	16 Sep 2020 14:00:52

US3742384

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:07

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:00:52

US3742384

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:00:52

US3742384

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:00:52

US3742384

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:07

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:00:52

US3742384

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:07

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:00:52

US3742384

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:07

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	16 Sep 2020 11:34:19

US3742384

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:07

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:00:56

US3742384

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:00:56

US3742384

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:14:07

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:42:12

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:14:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 14:45:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 14:45:40
Data point term sent to Coder	System	16 Sep 2020 14:45:19
User entered 'HYPERTENSION'	Hassan Haji (b) (4)	16 Sep 2020 14:44:59
	(b) (4)	

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '30 Jun 2017'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:14:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:14:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Jun 2017'	System	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '2017'	System	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:14:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Immune disorders NEC, HLT: Acute and chronic sarcoidosis, PT: Sarcoidosis, LLT: Sarcoidosis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 14:46:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 14:46:37
Data point term sent to Coder	System	16 Sep 2020 14:46:20
User entered 'SARCOIDOSIS'	Hassan Haji (b) (4)	16 Sep 2020 14:45:33
	(b) (4)	

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:45:33

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:45:33

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:14:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:45:33

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:45:33

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:14:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:45:33

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	16 Sep 2020 14:45:33

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '2019'	System	16 Sep 2020 14:45:33

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:45:33

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:45:33

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '08:18'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '16 Sep 2020 08:18'	System	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '64.5' in	Hassan Haji (b) (4)	16 Sep 2020 15:05:44
DataPoint set to visible.	(b) (4) System	16 Sep 2020 14:00:56

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '241.0' lb	Hassan Haji (b) (4)	16 Sep 2020 15:05:44
DataPoint set to visible.	(b) (4) System	16 Sep 2020 14:00:56

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '40.81384'	System	16 Sep 2020 15:05:44
DataPoint set to visible.	System	16 Sep 2020 14:00:56

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	16 Sep 2020 15:05:44
DataPoint set to visible.	System	16 Sep 2020 14:00:56

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:05:52

US3742384

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:05:52

US3742384

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:14:07

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:06:42

US3742384

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:06:42

US3742384

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:06:42

US3742384

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:06:42

US3742384

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:06:42

US3742384

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:14:07

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:06:42

US3742384

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:06:42

US3742384

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:14:07

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:06:42

US3742384

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 13:37:56

US3742384

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Date of test \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 13:37:56

US3742384

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Test performed](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 13:38:02
User entered 'Urine (URINE)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 13:38:02
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 13:37:56
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 13:37:56

US3742384

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	30 Sep 2020 13:37:56

US3742384

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 13:37:56

US3742384

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 13:37:56

US3742384

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 13:37:56

US3742384

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 13:37:56

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

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)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

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)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

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)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

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)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

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)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

Other

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

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'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

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'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:07

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:14:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:07:03

US3742384

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:07:03

US3742384

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:07:03

US3742384

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:14:07

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	16 Sep 2020 15:07:03

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '16 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	16 Sep 2020 13:39:55

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '190964'	RWS_ENDPOINT ENDPOINT (b) (4) 	16 Sep 2020 13:39:55

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	16 Sep 2020 13:39:55

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:07

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)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:07:35

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:07:35

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:07:35

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:07

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:07:35

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:07

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:07:35

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 13:38:46
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:18:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:18:55

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:14:07

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:14:07

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:14:07

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:14:07

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '08:18'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '16 Sep 2020 08:18'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '098.9' F	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '092'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '12'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '127'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '086'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:14:07

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:14:07

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '10:23'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '16 Sep 2020 10:23'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '99.2' F	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '096'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '16'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '128'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '085'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:35

US3742384

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:35

US3742384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 13:38:33
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:17:27

US3742384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 13:38:33
User entered '16 Sep 2020'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:17:27

US3742384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Test performed](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 13:38:33
User entered 'Urine (URINE)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:17:27

US3742384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Result](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 13:38:33
User entered 'Negative (NEGATIVE)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:17:27

US3742384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User closed query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 15:56:28
Query 'per CDM: please input yes or no in this field' answered with 'updateded' (Site from DM).	Sherry McCammon (b) (4)	12 Oct 2020 13:00:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 12:59:42
User opened query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 14:32:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 13:38:33
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 15:17:27
	(b) (4)	

US3742384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:17:27

US3742384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:17:27

US3742384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 15:17:27

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '09:53'	(b) (4), (b) (6)	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '16 Sep 2020 09:53'	System	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:17:54

US3742384

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:17:54

US3742384

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:07

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '08:44'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:17:54

US3742384

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '16 Sep 2020 08:44'	System	16 Sep 2020 15:17:54

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:18:19

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:14:07

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:18:19

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:14:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:18:19

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:14:07

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '08:47'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:18:19

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '16 Sep 2020 08:47'	System	16 Sep 2020 15:18:19

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:14:07

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:18:19

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:14:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:18:19

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:14:07

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:18:19

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 15:18:19

US3742384

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:18:40

US3742384

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 15:18:40

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:23:20', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5f10a47d-4710-4fc3-9c40-21dfd69064a2'	System	16 Sep 2020 14:23:50
User entered 'Yes (Y)'	System	16 Sep 2020 14:23:50

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:23:24', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5f10a47d-4710-4fc3-9c40-21dfd69064a2'	System	16 Sep 2020 14:23:50
User entered '99.2'	System	16 Sep 2020 14:23:50

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:23:34', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5f10a47d-4710-4fc3-9c40-21dfd69064a2'	System	16 Sep 2020 14:23:50
User entered 'No (N)'	System	16 Sep 2020 14:23:50

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:23:47', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5f10a47d-4710-4fc3-9c40-21dfd69064a2'	System	16 Sep 2020 14:23:50
User entered '16 Sep 2020 10:23'	System	16 Sep 2020 14:23:50

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 10:13'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:43'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:37', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b4e56fea-c717-4741-961a-16bd1ac4763d'	System	17 Sep 2020 05:49:03
User entered 'Yes (Y)'	System	17 Sep 2020 05:49:03

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:42', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b4e56fea-c717-4741-961a-16bd1ac4763d'	System	17 Sep 2020 05:49:03
User entered '97.7'	System	17 Sep 2020 05:49:03

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:54', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b4e56fea-c717-4741-961a-16bd1ac4763d'	System	17 Sep 2020 05:49:03
User entered 'No (N)'	System	17 Sep 2020 05:49:03

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:49:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b4e56fea-c717-4741-961a-16bd1ac4763d'	System	17 Sep 2020 05:49:03
User entered '17 Sep 2020 01:49'	System	17 Sep 2020 05:49:03

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 13:38'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 2'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:27:20', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '9628657f-7db9-456a-a32f-2c5290785945'	System	17 Sep 2020 21:27:48
User entered 'Yes (Y)'	System	17 Sep 2020 21:27:48

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:27:27', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '9628657f-7db9-456a-a32f-2c5290785945'	System	17 Sep 2020 21:27:48
User entered '98.2'	System	17 Sep 2020 21:27:48

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:27:39', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '9628657f-7db9-456a-a32f-2c5290785945'	System	17 Sep 2020 21:27:48
User entered 'No (N)'	System	17 Sep 2020 21:27:48

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:27:44', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '9628657f-7db9-456a-a32f-2c5290785945'	System	17 Sep 2020 21:27:48
User entered '17 Sep 2020 17:27'	System	17 Sep 2020 21:27:48

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 3'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:14:38', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '131c9fa5-54e2-4641-8639-ff72eaf1f92d'	System	19 Sep 2020 13:14:54
User entered 'Yes (Y)'	System	19 Sep 2020 13:14:54

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:14:44', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '131c9fa5-54e2-4641-8639-ff72eaf1f92d'	System	19 Sep 2020 13:14:54
User entered '98.2'	System	19 Sep 2020 13:14:54

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:14:48', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '131c9fa5-54e2-4641-8639-ff72eaf1f92d'	System	19 Sep 2020 13:14:54
User entered 'No (N)'	System	19 Sep 2020 13:14:54

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:14:50', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '131c9fa5-54e2-4641-8639-ff72eaf1f92d'	System	19 Sep 2020 13:14:54
User entered '19 Sep 2020 09:14'	System	19 Sep 2020 13:14:54

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 4'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:42:57', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd01db338-db60-4c7b-8383-7270718c1015'	System	19 Sep 2020 21:43:26
User entered 'Yes (Y)'	System	19 Sep 2020 21:43:26

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:43:03', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd01db338-db60-4c7b-8383-7270718c1015'	System	19 Sep 2020 21:43:26
User entered '98.8'	System	19 Sep 2020 21:43:26

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:43:10', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd01db338-db60-4c7b-8383-7270718c1015'	System	19 Sep 2020 21:43:26
User entered 'No (N)'	System	19 Sep 2020 21:43:26

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:43:22', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd01db338-db60-4c7b-8383-7270718c1015'	System	19 Sep 2020 21:43:26
User entered '19 Sep 2020 17:43'	System	19 Sep 2020 21:43:26

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 5'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:45:24', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8924a04c-9500-445c-8779-fda2c0323f12'	System	21 Sep 2020 00:45:37
User entered 'Yes (Y)'	System	21 Sep 2020 00:45:37

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:45:29', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8924a04c-9500-445c-8779-fda2c0323f12'	System	21 Sep 2020 00:45:37
User entered '98.1'	System	21 Sep 2020 00:45:37

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:45:32', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8924a04c-9500-445c-8779-fda2c0323f12'	System	21 Sep 2020 00:45:37
User entered 'No (N)'	System	21 Sep 2020 00:45:37

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:45:34', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8924a04c-9500-445c-8779-fda2c0323f12'	System	21 Sep 2020 00:45:37
User entered '20 Sep 2020 20:45'	System	21 Sep 2020 00:45:37

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 6'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:30:36', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '16fd6c6a-cdd7-4b0f-ac0b-c89beb632b30'	System	21 Sep 2020 21:31:10
User entered 'Yes (Y)'	System	21 Sep 2020 21:31:10

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:30:39', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '16fd6c6a-cdd7-4b0f-ac0b-c89beb632b30'	System	21 Sep 2020 21:31:10
User entered '98.7'	System	21 Sep 2020 21:31:10

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:02', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '16fd6c6a-cdd7-4b0f-ac0b-c89beb632b30'	System	21 Sep 2020 21:31:10
User entered 'No (N)'	System	21 Sep 2020 21:31:10

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:05', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '16fd6c6a-cdd7-4b0f-ac0b-c89beb632b30'	System	21 Sep 2020 21:31:10
User entered '21 Sep 2020 17:31'	System	21 Sep 2020 21:31:10

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 7'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:04:25', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4b0838b3-7d9c-4def-a617-b875513b9034'	System	22 Sep 2020 21:04:41
User entered 'Yes (Y)'	System	22 Sep 2020 21:04:41

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:04:28', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4b0838b3-7d9c-4def-a617-b875513b9034'	System	22 Sep 2020 21:04:41
User entered '98.4'	System	22 Sep 2020 21:04:41

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:04:34', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4b0838b3-7d9c-4def-a617-b875513b9034'	System	22 Sep 2020 21:04:41
User entered 'No (N)'	System	22 Sep 2020 21:04:41

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:04:37', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4b0838b3-7d9c-4def-a617-b875513b9034'	System	22 Sep 2020 21:04:41
User entered '22 Sep 2020 17:04'	System	22 Sep 2020 21:04:41

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-16T10:24:57', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '42150791-320d-492e-a7f0-6e7492eb3ecb'	System	16 Sep 2020 14:25:19
User entered 'None (1)'	System	16 Sep 2020 14:25:19

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:25:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '42150791-320d-492e-a7f0-6e7492eb3ecb'	System	16 Sep 2020 14:25:19
User entered 'No (N)'	System	16 Sep 2020 14:25:19

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:25:04', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '42150791-320d-492e-a7f0-6e7492eb3ecb'	System	16 Sep 2020 14:25:19
User entered 'No (N)'	System	16 Sep 2020 14:25:19

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-16T10:25:10', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '42150791-320d-492e-a7f0-6e7492eb3ecb'	System	16 Sep 2020 14:25:19
User entered 'None (1)'	System	16 Sep 2020 14:25:19

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:25:15', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '42150791-320d-492e-a7f0-6e7492eb3ecb'	System	16 Sep 2020 14:25:19
User entered '16 Sep 2020 10:25'	System	16 Sep 2020 14:25:19

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 10:13'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:43'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-17T01:47:29', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '99d4948a-16fc-4fc0-9508-145c9cb670e9'	System	17 Sep 2020 05:47:58
User entered 'None (1)'	System	17 Sep 2020 05:47:58

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:47:32', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '99d4948a-16fc-4fc0-9508-145c9cb670e9'	System	17 Sep 2020 05:47:58
User entered 'No (N)'	System	17 Sep 2020 05:47:58

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:47:35', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '99d4948a-16fc-4fc0-9508-145c9cb670e9'	System	17 Sep 2020 05:47:58
User entered 'No (N)'	System	17 Sep 2020 05:47:58

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-17T01:47:52', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '99d4948a-16fc-4fc0-9508-145c9cb670e9'	System	17 Sep 2020 05:47:58
User entered 'None (1)'	System	17 Sep 2020 05:47:58

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:47:55', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '99d4948a-16fc-4fc0-9508-145c9cb670e9'	System	17 Sep 2020 05:47:58
User entered '17 Sep 2020 01:47'	System	17 Sep 2020 05:47:58

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 13:38'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 2'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:20', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '7393e8b8-23f8-46c9-a9f7-b2c908a4794a'	System	17 Sep 2020 21:28:40
User entered 'None (1)'	System	17 Sep 2020 21:28:40

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:22', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '7393e8b8-23f8-46c9-a9f7-b2c908a4794a'	System	17 Sep 2020 21:28:40
User entered 'No (N)'	System	17 Sep 2020 21:28:40

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:25', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '7393e8b8-23f8-46c9-a9f7-b2c908a4794a'	System	17 Sep 2020 21:28:40
User entered 'No (N)'	System	17 Sep 2020 21:28:40

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:33', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '7393e8b8-23f8-46c9-a9f7-b2c908a4794a'	System	17 Sep 2020 21:28:40
User entered 'None (1)'	System	17 Sep 2020 21:28:40

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:36', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '7393e8b8-23f8-46c9-a9f7-b2c908a4794a'	System	17 Sep 2020 21:28:40
User entered '17 Sep 2020 17:28'	System	17 Sep 2020 21:28:40

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 3'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:24', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '76f9b5a3-57ef-47e2-a660-68e248fc0891'	System	19 Sep 2020 13:15:50
User entered 'None (1)'	System	19 Sep 2020 13:15:50

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:28', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '76f9b5a3-57ef-47e2-a660-68e248fc0891'	System	19 Sep 2020 13:15:50
User entered 'No (N)'	System	19 Sep 2020 13:15:50

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:32', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '76f9b5a3-57ef-47e2-a660-68e248fc0891'	System	19 Sep 2020 13:15:50
User entered 'No (N)'	System	19 Sep 2020 13:15:50

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:39', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '76f9b5a3-57ef-47e2-a660-68e248fc0891'	System	19 Sep 2020 13:15:50
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 13:15:50

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:46', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '76f9b5a3-57ef-47e2-a660-68e248fc0891'	System	19 Sep 2020 13:15:50
User entered '19 Sep 2020 09:15'	System	19 Sep 2020 13:15:50

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 4'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-19T17:43:44', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f48c3e4a-74b7-4534-b6a7-04dbfa14ade4'	System	19 Sep 2020 21:44:26
User entered 'None (1)'	System	19 Sep 2020 21:44:26

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:43:48', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f48c3e4a-74b7-4534-b6a7-04dbfa14ade4'	System	19 Sep 2020 21:44:26
User entered 'No (N)'	System	19 Sep 2020 21:44:26

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:10', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f48c3e4a-74b7-4534-b6a7-04dbfa14ade4'	System	19 Sep 2020 21:44:26
User entered 'No (N)'	System	19 Sep 2020 21:44:26

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:13', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f48c3e4a-74b7-4534-b6a7-04dbfa14ade4'	System	19 Sep 2020 21:44:26
User entered 'None (1)'	System	19 Sep 2020 21:44:26

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:22', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f48c3e4a-74b7-4534-b6a7-04dbfa14ade4'	System	19 Sep 2020 21:44:26
User entered '19 Sep 2020 17:44'	System	19 Sep 2020 21:44:26

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 5'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-20T20:45:39', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '702bcf75-9ed9-440e-b4ae-0bf1c8e9e034'	System	21 Sep 2020 00:46:06
User entered 'None (1)'	System	21 Sep 2020 00:46:06

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:45:41', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '702bcf75-9ed9-440e-b4ae-0bf1c8e9e034'	System	21 Sep 2020 00:46:06
User entered 'No (N)'	System	21 Sep 2020 00:46:06

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:45:49', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '702bcf75-9ed9-440e-b4ae-0bf1c8e9e034'	System	21 Sep 2020 00:46:06
User entered 'No (N)'	System	21 Sep 2020 00:46:06

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-20T20:45:58', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '702bcf75-9ed9-440e-b4ae-0bf1c8e9e034'	System	21 Sep 2020 00:46:06
User entered 'None (1)'	System	21 Sep 2020 00:46:06

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:46:01', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '702bcf75-9ed9-440e-b4ae-0bf1c8e9e034'	System	21 Sep 2020 00:46:06
User entered '20 Sep 2020 20:46'	System	21 Sep 2020 00:46:06

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 6'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:34', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'bd31e728-2462-4f0f-80ca-bf5ab92f35ff'	System	21 Sep 2020 21:31:54
User entered 'None (1)'	System	21 Sep 2020 21:31:54

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:39', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'bd31e728-2462-4f0f-80ca-bf5ab92f35ff'	System	21 Sep 2020 21:31:54
User entered 'No (N)'	System	21 Sep 2020 21:31:54

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:40', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'bd31e728-2462-4f0f-80ca-bf5ab92f35ff'	System	21 Sep 2020 21:31:54
User entered 'No (N)'	System	21 Sep 2020 21:31:54

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:47', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'bd31e728-2462-4f0f-80ca-bf5ab92f35ff'	System	21 Sep 2020 21:31:54
User entered 'None (1)'	System	21 Sep 2020 21:31:54

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:50', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'bd31e728-2462-4f0f-80ca-bf5ab92f35ff'	System	21 Sep 2020 21:31:54
User entered '21 Sep 2020 17:31'	System	21 Sep 2020 21:31:54

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 7'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:07

[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 (d06fb84cf1d8da2d)', Time: '2020-09-22T17:04:52', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a977443f-b8c3-41f9-af6f-b461fe43a42d'	System	22 Sep 2020 21:05:05
User entered 'None (1)'	System	22 Sep 2020 21:05:05

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:04:54', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a977443f-b8c3-41f9-af6f-b461fe43a42d'	System	22 Sep 2020 21:05:05
User entered 'No (N)'	System	22 Sep 2020 21:05:05

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:04:57', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a977443f-b8c3-41f9-af6f-b461fe43a42d'	System	22 Sep 2020 21:05:05
User entered 'No (N)'	System	22 Sep 2020 21:05:05

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-22T17:04:59', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a977443f-b8c3-41f9-af6f-b461fe43a42d'	System	22 Sep 2020 21:05:05
User entered 'None (1)'	System	22 Sep 2020 21:05:05

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:05:01', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a977443f-b8c3-41f9-af6f-b461fe43a42d'	System	22 Sep 2020 21:05:05
User entered '22 Sep 2020 17:05'	System	22 Sep 2020 21:05:05

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:27:35', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e57ed8b0-90f0-4692-915a-e28eea195e27'	System	16 Sep 2020 14:28:03
User entered 'None (0)'	System	16 Sep 2020 14:28:03

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:27:36', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e57ed8b0-90f0-4692-915a-e28eea195e27'	System	16 Sep 2020 14:28:03
User entered 'None (0)'	System	16 Sep 2020 14:28:03

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:27:38', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e57ed8b0-90f0-4692-915a-e28eea195e27'	System	16 Sep 2020 14:28:03
User entered 'None (0)'	System	16 Sep 2020 14:28:03

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:27:39', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e57ed8b0-90f0-4692-915a-e28eea195e27'	System	16 Sep 2020 14:28:03
User entered 'None (0)'	System	16 Sep 2020 14:28:03

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:27:41', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e57ed8b0-90f0-4692-915a-e28eea195e27'	System	16 Sep 2020 14:28:03
User entered 'None (0)'	System	16 Sep 2020 14:28:03

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:27:42', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e57ed8b0-90f0-4692-915a-e28eea195e27'	System	16 Sep 2020 14:28:03
User entered 'None (0)'	System	16 Sep 2020 14:28:03

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-16T10:27:45', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e57ed8b0-90f0-4692-915a-e28eea195e27'	System	16 Sep 2020 14:28:03
User entered 'No (N)'	System	16 Sep 2020 14:28:03

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:27:49', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e57ed8b0-90f0-4692-915a-e28eea195e27'	System	16 Sep 2020 14:28:03
User entered '16 Sep 2020 10:27'	System	16 Sep 2020 14:28:03

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 10:13'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:43'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:47:59', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f196e41e-bd1f-49c6-8146-de039e1b0fa6'	System	17 Sep 2020 05:48:19
User entered 'None (0)'	System	17 Sep 2020 05:48:19

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f196e41e-bd1f-49c6-8146-de039e1b0fa6'	System	17 Sep 2020 05:48:19
User entered 'None (0)'	System	17 Sep 2020 05:48:19

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:02', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f196e41e-bd1f-49c6-8146-de039e1b0fa6'	System	17 Sep 2020 05:48:19
User entered 'None (0)'	System	17 Sep 2020 05:48:19

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:04', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f196e41e-bd1f-49c6-8146-de039e1b0fa6'	System	17 Sep 2020 05:48:19
User entered 'None (0)'	System	17 Sep 2020 05:48:19

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:05', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f196e41e-bd1f-49c6-8146-de039e1b0fa6'	System	17 Sep 2020 05:48:19
User entered 'None (0)'	System	17 Sep 2020 05:48:19

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:07', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f196e41e-bd1f-49c6-8146-de039e1b0fa6'	System	17 Sep 2020 05:48:19
User entered 'None (0)'	System	17 Sep 2020 05:48:19

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:12', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f196e41e-bd1f-49c6-8146-de039e1b0fa6'	System	17 Sep 2020 05:48:19
User entered 'No (N)'	System	17 Sep 2020 05:48:19

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:16', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f196e41e-bd1f-49c6-8146-de039e1b0fa6'	System	17 Sep 2020 05:48:19
User entered '17 Sep 2020 01:48'	System	17 Sep 2020 05:48:19

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 13:38'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 2'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:27:59', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd9bece71-4402-4ef0-aad8-f2d70c7671ec'	System	17 Sep 2020 21:28:22
User entered 'No interference with activity (1)'	System	17 Sep 2020 21:28:22

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:01', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd9bece71-4402-4ef0-aad8-f2d70c7671ec'	System	17 Sep 2020 21:28:22
User entered 'None (0)'	System	17 Sep 2020 21:28:22

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:03', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd9bece71-4402-4ef0-aad8-f2d70c7671ec'	System	17 Sep 2020 21:28:22
User entered 'None (0)'	System	17 Sep 2020 21:28:22

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:05', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd9bece71-4402-4ef0-aad8-f2d70c7671ec'	System	17 Sep 2020 21:28:22
User entered 'None (0)'	System	17 Sep 2020 21:28:22

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:06', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd9bece71-4402-4ef0-aad8-f2d70c7671ec'	System	17 Sep 2020 21:28:22
User entered 'None (0)'	System	17 Sep 2020 21:28:22

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:08', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd9bece71-4402-4ef0-aad8-f2d70c7671ec'	System	17 Sep 2020 21:28:22
User entered 'None (0)'	System	17 Sep 2020 21:28:22

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:14', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd9bece71-4402-4ef0-aad8-f2d70c7671ec'	System	17 Sep 2020 21:28:22
User entered 'No (N)'	System	17 Sep 2020 21:28:22

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:16', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd9bece71-4402-4ef0-aad8-f2d70c7671ec'	System	17 Sep 2020 21:28:22
User entered '17 Sep 2020 17:28'	System	17 Sep 2020 21:28:22

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 3'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:14:55', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'ac692baf-fa1a-4694-8f9d-a4aa56328eb5'	System	19 Sep 2020 13:15:24
User entered 'No interference with activity (1)'	System	19 Sep 2020 13:15:24

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:14:58', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'ac692baf-fa1a-4694-8f9d-a4aa56328eb5'	System	19 Sep 2020 13:15:24
User entered 'None (0)'	System	19 Sep 2020 13:15:24

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:03', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'ac692baf-fa1a-4694-8f9d-a4aa56328eb5'	System	19 Sep 2020 13:15:24
User entered 'None (0)'	System	19 Sep 2020 13:15:24

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:09', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'ac692baf-fa1a-4694-8f9d-a4aa56328eb5'	System	19 Sep 2020 13:15:24
User entered 'None (0)'	System	19 Sep 2020 13:15:24

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:12', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'ac692baf-fa1a-4694-8f9d-a4aa56328eb5'	System	19 Sep 2020 13:15:24
User entered 'None (0)'	System	19 Sep 2020 13:15:24

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:14', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'ac692baf-fa1a-4694-8f9d-a4aa56328eb5'	System	19 Sep 2020 13:15:24
User entered 'None (0)'	System	19 Sep 2020 13:15:24

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:18', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'ac692baf-fa1a-4694-8f9d-a4aa56328eb5'	System	19 Sep 2020 13:15:24
User entered 'No (N)'	System	19 Sep 2020 13:15:24

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:20', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'ac692baf-fa1a-4694-8f9d-a4aa56328eb5'	System	19 Sep 2020 13:15:24
User entered '19 Sep 2020 09:15'	System	19 Sep 2020 13:15:24

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 4'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:32', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c6579292-8de6-40c8-8d6d-12534673d76b'	System	19 Sep 2020 21:44:57
User entered 'None (0)'	System	19 Sep 2020 21:44:57

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:41', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c6579292-8de6-40c8-8d6d-12534673d76b'	System	19 Sep 2020 21:44:57
User entered 'None (0)'	System	19 Sep 2020 21:44:57

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:42', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c6579292-8de6-40c8-8d6d-12534673d76b'	System	19 Sep 2020 21:44:57
User entered 'None (0)'	System	19 Sep 2020 21:44:57

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:44', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c6579292-8de6-40c8-8d6d-12534673d76b'	System	19 Sep 2020 21:44:57
User entered 'None (0)'	System	19 Sep 2020 21:44:57

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:45', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c6579292-8de6-40c8-8d6d-12534673d76b'	System	19 Sep 2020 21:44:57
User entered 'None (0)'	System	19 Sep 2020 21:44:57

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:47', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c6579292-8de6-40c8-8d6d-12534673d76b'	System	19 Sep 2020 21:44:57
User entered 'None (0)'	System	19 Sep 2020 21:44:57

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:50', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c6579292-8de6-40c8-8d6d-12534673d76b'	System	19 Sep 2020 21:44:57
User entered 'No (N)'	System	19 Sep 2020 21:44:57

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:54', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c6579292-8de6-40c8-8d6d-12534673d76b'	System	19 Sep 2020 21:44:57
User entered '19 Sep 2020 17:44'	System	19 Sep 2020 21:44:57

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 5'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:46:07', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a241dce3-ebc5-41e3-bacd-cf39d42f0da3'	System	21 Sep 2020 00:46:38
User entered 'None (0)'	System	21 Sep 2020 00:46:38

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:46:09', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a241dce3-ebc5-41e3-bacd-cf39d42f0da3'	System	21 Sep 2020 00:46:38
User entered 'None (0)'	System	21 Sep 2020 00:46:38

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:46:12', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a241dce3-ebc5-41e3-bacd-cf39d42f0da3'	System	21 Sep 2020 00:46:38
User entered 'None (0)'	System	21 Sep 2020 00:46:38

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:46:23', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a241dce3-ebc5-41e3-bacd-cf39d42f0da3'	System	21 Sep 2020 00:46:38
User entered 'None (0)'	System	21 Sep 2020 00:46:38

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:46:25', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a241dce3-ebc5-41e3-bacd-cf39d42f0da3'	System	21 Sep 2020 00:46:38
User entered 'None (0)'	System	21 Sep 2020 00:46:38

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:46:27', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a241dce3-ebc5-41e3-bacd-cf39d42f0da3'	System	21 Sep 2020 00:46:38
User entered 'None (0)'	System	21 Sep 2020 00:46:38

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-20T20:46:31', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a241dce3-ebc5-41e3-bacd-cf39d42f0da3'	System	21 Sep 2020 00:46:38
User entered 'No (N)'	System	21 Sep 2020 00:46:38

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:46:35', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a241dce3-ebc5-41e3-bacd-cf39d42f0da3'	System	21 Sep 2020 00:46:38
User entered '20 Sep 2020 20:46'	System	21 Sep 2020 00:46:38

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 6'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:55', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5e1c36c3-4c98-4553-92a9-3f8f46da2be4'	System	21 Sep 2020 21:32:25
User entered 'None (0)'	System	21 Sep 2020 21:32:25

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:57', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5e1c36c3-4c98-4553-92a9-3f8f46da2be4'	System	21 Sep 2020 21:32:25
User entered 'None (0)'	System	21 Sep 2020 21:32:25

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:58', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5e1c36c3-4c98-4553-92a9-3f8f46da2be4'	System	21 Sep 2020 21:32:25
User entered 'None (0)'	System	21 Sep 2020 21:32:25

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:32:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5e1c36c3-4c98-4553-92a9-3f8f46da2be4'	System	21 Sep 2020 21:32:25
User entered 'None (0)'	System	21 Sep 2020 21:32:25

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:32:02', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5e1c36c3-4c98-4553-92a9-3f8f46da2be4'	System	21 Sep 2020 21:32:25
User entered 'None (0)'	System	21 Sep 2020 21:32:25

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:32:03', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5e1c36c3-4c98-4553-92a9-3f8f46da2be4'	System	21 Sep 2020 21:32:25
User entered 'None (0)'	System	21 Sep 2020 21:32:25

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-21T17:32:11', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5e1c36c3-4c98-4553-92a9-3f8f46da2be4'	System	21 Sep 2020 21:32:25
User entered 'No (N)'	System	21 Sep 2020 21:32:25

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:32:22', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5e1c36c3-4c98-4553-92a9-3f8f46da2be4'	System	21 Sep 2020 21:32:25
User entered '21 Sep 2020 17:32'	System	21 Sep 2020 21:32:25

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 7'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:05:04', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '49cb7f72-0879-4f41-b74d-912d1ce121d5'	System	22 Sep 2020 21:05:21
User entered 'None (0)'	System	22 Sep 2020 21:05:21

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:05:06', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '49cb7f72-0879-4f41-b74d-912d1ce121d5'	System	22 Sep 2020 21:05:21
User entered 'None (0)'	System	22 Sep 2020 21:05:21

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:05:08', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '49cb7f72-0879-4f41-b74d-912d1ce121d5'	System	22 Sep 2020 21:05:21
User entered 'None (0)'	System	22 Sep 2020 21:05:21

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:05:09', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '49cb7f72-0879-4f41-b74d-912d1ce121d5'	System	22 Sep 2020 21:05:21
User entered 'None (0)'	System	22 Sep 2020 21:05:21

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:05:10', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '49cb7f72-0879-4f41-b74d-912d1ce121d5'	System	22 Sep 2020 21:05:21
User entered 'None (0)'	System	22 Sep 2020 21:05:21

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:05:12', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '49cb7f72-0879-4f41-b74d-912d1ce121d5'	System	22 Sep 2020 21:05:21
User entered 'None (0)'	System	22 Sep 2020 21:05:21

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-09-22T17:05:13', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '49cb7f72-0879-4f41-b74d-912d1ce121d5'	System	22 Sep 2020 21:05:21
User entered 'No (N)'	System	22 Sep 2020 21:05:21

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:05:17', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '49cb7f72-0879-4f41-b74d-912d1ce121d5'	System	22 Sep 2020 21:05:21
User entered '22 Sep 2020 17:05'	System	22 Sep 2020 21:05:21

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Sep 2020 15:30:53
	(b) (4)	

US3742384

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Sherry McCammon (b) (4)	23 Sep 2020 15:30:53
	(b) (4)	

US3742384

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	23 Sep 2020 15:30:53

US3742384

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	23 Sep 2020 15:30:53
	(b) (4)	

US3742384

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Sep 2020 15:31:02
	(b) (4)	

US3742384

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 15:31:02

US3742384

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 13:37:02

US3742384

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 13:37:02

US3742384

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Sep 2020 13:37:02

US3742384

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 13:37:02

US3742384

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 13:37:07

US3742384

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 13:37:07

US3742384

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:47:53

US3742384

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '7 Oct 2020'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:47:53

US3742384

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:47:53

US3742384

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:47:53

US3742384

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:47:58

US3742384

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:47:58

US3742384

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 12:25:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 12:25:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 12:25:09
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 12:24:43
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 12:24:43

US3742384

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 12:24:43

US3742384

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Oct 2020 12:24:43

US3742384

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:07

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	13 Oct 2020 12:25:09
User entered empty.	System	13 Oct 2020 12:24:43

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '07:30'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 07:30'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '100.0' F	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '108'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '16'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '122'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '080'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '08:51'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 08:51'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '99.2' F	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '115'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '16'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '153'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '072'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 12:27:04

US3742384

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 12:27:04

US3742384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 12:27:59

US3742384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 12:27:59

US3742384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	(b) (4), (b) (6)	13 Oct 2020 12:27:59

US3742384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	13 Oct 2020 12:27:59

US3742384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User closed query 'per CDM: if FSH sample was not collected, the collection date and time fields should be blank - please use the drop down menu to remove data, or clarify' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:53:16
Query 'per CDM: if FSH sample was not collected, the collection date and time fields should be blank - please use the drop down menu to remove data, or clarify' answered with 'Date/time removed' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 20:37:05
User opened query 'per CDM: if FSH sample was not collected, the collection date and time fields should be blank - please use the drop down menu to remove data, or clarify' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 13:35:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 12:27:59

US3742384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Collection date](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:37:08
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 12:27:59

US3742384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

[Collection time](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:37:08
User entered '07:30'	(b) (4), (b) (6)	13 Oct 2020 12:27:59

US3742384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 20:37:08
User entered '13 Oct 2020 07:30'	System	13 Oct 2020 12:27:59

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '08:19'	(b) (4), (b) (6)	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 08:19'	System	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 12:28:17

US3742384

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 11:46:07
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'PER SPONSOR - OK TO USE DAY 29 LAB FOR UNSCHEDULED VISIT AS WELL. SAMPLE IS SUITABLE FOR BOTH EVENTS. ' (Site from DM).	Kaitlin Mason (b) (4)	24 Oct 2020 14:08:44
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:13:58
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:11:06
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 09:01:24
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 12:28:17

US3742384

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '07:59'	(b) (4), (b) (6)	13 Oct 2020 12:28:17

US3742384

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 07:59'	System	13 Oct 2020 12:28:17

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:14:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 13OCT2020is recorded under Visit 2 Day 29 in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 12:04:57
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 13OCT2020is recorded under Visit 2 Day 29 in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' answered with 'Unscheduled Visit kit used for Day 29 visit due to shortage of Kit A at site. Confirmed that sample is for D29, NOT unscheduled visit. ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	30 Oct 2020 14:56:18
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 13OCT2020is recorded under Visit 2 Day 29 in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 12:06:53
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 12:28:37

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:14:07

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	13 Oct 2020 12:28:37

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:14:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 12:28:37

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:14:07

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '07:57'	(b) (4), (b) (6)	13 Oct 2020 12:28:37

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 07:57'	System	13 Oct 2020 12:28:37

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:14:07

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	13 Oct 2020 12:28:37

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:14:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 12:28:37

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:14:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 12:28:37

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 12:28:37

US3742384

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 13:53:08

US3742384

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 13:53:08

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:09', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4261cc8f-c035-4eb5-a2da-c6d9bb8bba8c'	System	13 Oct 2020 13:00:38
User entered 'Yes (Y)'	System	13 Oct 2020 13:00:38

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:17', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4261cc8f-c035-4eb5-a2da-c6d9bb8bba8c'	System	13 Oct 2020 13:00:38
User entered '99.2'	System	13 Oct 2020 13:00:38

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:20', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4261cc8f-c035-4eb5-a2da-c6d9bb8bba8c'	System	13 Oct 2020 13:00:38
User entered 'Yes (Y)'	System	13 Oct 2020 13:00:38

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Ibuprofen 400mg po prn for pain.' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 11:08:34
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	13 Oct 2020 13:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:27', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4261cc8f-c035-4eb5-a2da-c6d9bb8bba8c'	System	13 Oct 2020 13:00:38
User entered '1'	System	13 Oct 2020 13:00:38

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:27', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4261cc8f-c035-4eb5-a2da-c6d9bb8bba8c'	System	13 Oct 2020 13:00:38
User entered '0'	System	13 Oct 2020 13:00:38

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:30', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4261cc8f-c035-4eb5-a2da-c6d9bb8bba8c'	System	13 Oct 2020 13:00:38
User entered '13 Oct 2020 09:00'	System	13 Oct 2020 13:00:38

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 08:39'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:09'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:43:39', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '59f8135c-2bc0-43d5-993e-cf6ff8ce1a39'	System	14 Oct 2020 12:44:08
User entered 'Yes (Y)'	System	14 Oct 2020 12:44:08

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:43:48', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '59f8135c-2bc0-43d5-993e-cf6ff8ce1a39'	System	14 Oct 2020 12:44:08
User entered '98.2'	System	14 Oct 2020 12:44:08

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:43:55', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '59f8135c-2bc0-43d5-993e-cf6ff8ce1a39'	System	14 Oct 2020 12:44:08
User entered 'Yes (Y)'	System	14 Oct 2020 12:44:08

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Ibuprofen 400mg po prn for pain.' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 11:09:27
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	14 Oct 2020 12:44:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '59f8135c-2bc0-43d5-993e-cf6ff8ce1a39'	System	14 Oct 2020 12:44:08
User entered '1'	System	14 Oct 2020 12:44:08

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '59f8135c-2bc0-43d5-993e-cf6ff8ce1a39'	System	14 Oct 2020 12:44:08
User entered '0'	System	14 Oct 2020 12:44:08

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:02', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '59f8135c-2bc0-43d5-993e-cf6ff8ce1a39'	System	14 Oct 2020 12:44:08
User entered '14 Oct 2020 08:44'	System	14 Oct 2020 12:44:08

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:04'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 2'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T07:14:48', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fbfa7849-bbbc-405c-957e-f7288d191aa3'	System	15 Oct 2020 11:15:06
User entered 'Yes (Y)'	System	15 Oct 2020 11:15:06

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T07:14:53', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fbfa7849-bbbc-405c-957e-f7288d191aa3'	System	15 Oct 2020 11:15:06
User entered '97.9'	System	15 Oct 2020 11:15:06

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T07:14:56', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fbfa7849-bbbc-405c-957e-f7288d191aa3'	System	15 Oct 2020 11:15:06
User entered 'No (N)'	System	15 Oct 2020 11:15:06

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T07:14:58', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fbfa7849-bbbc-405c-957e-f7288d191aa3'	System	15 Oct 2020 11:15:06
User entered '15 Oct 2020 07:14'	System	15 Oct 2020 11:15:06

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 3'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:12', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '56c65c36-5047-433b-97e8-1b293b956934'	System	15 Oct 2020 19:57:34
User entered 'Yes (Y)'	System	15 Oct 2020 19:57:34

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:16', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '56c65c36-5047-433b-97e8-1b293b956934'	System	15 Oct 2020 19:57:34
User entered '98.7'	System	15 Oct 2020 19:57:34

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:21', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '56c65c36-5047-433b-97e8-1b293b956934'	System	15 Oct 2020 19:57:34
User entered 'No (N)'	System	15 Oct 2020 19:57:34

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:25', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '56c65c36-5047-433b-97e8-1b293b956934'	System	15 Oct 2020 19:57:34
User entered '15 Oct 2020 15:57'	System	15 Oct 2020 19:57:34

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 4'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:21:35', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'eb2b231b-8267-49d0-8d15-228a91a24360'	System	16 Oct 2020 23:21:55
User entered 'Yes (Y)'	System	16 Oct 2020 23:21:55

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:21:38', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'eb2b231b-8267-49d0-8d15-228a91a24360'	System	16 Oct 2020 23:21:55
User entered '98.5'	System	16 Oct 2020 23:21:55

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:21:49', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'eb2b231b-8267-49d0-8d15-228a91a24360'	System	16 Oct 2020 23:21:55
User entered 'No (N)'	System	16 Oct 2020 23:21:55

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:21:51', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'eb2b231b-8267-49d0-8d15-228a91a24360'	System	16 Oct 2020 23:21:55
User entered '16 Oct 2020 19:21'	System	16 Oct 2020 23:21:55

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 5'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:44:56', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8a9274b2-fad8-4cee-9856-efbc11d9b803'	System	17 Oct 2020 22:46:12
User entered 'Yes (Y)'	System	17 Oct 2020 22:46:12

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:45:53', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8a9274b2-fad8-4cee-9856-efbc11d9b803'	System	17 Oct 2020 22:46:12
User entered '99.1'	System	17 Oct 2020 22:46:12

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:45:58', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8a9274b2-fad8-4cee-9856-efbc11d9b803'	System	17 Oct 2020 22:46:12
User entered 'Yes (Y)'	System	17 Oct 2020 22:46:12

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Ibuprofen 400mg po prn for pain.' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 11:09:35
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	17 Oct 2020 22:46:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:46:04', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8a9274b2-fad8-4cee-9856-efbc11d9b803'	System	17 Oct 2020 22:46:12
User entered '1'	System	17 Oct 2020 22:46:12

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:07

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:46:04', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8a9274b2-fad8-4cee-9856-efbc11d9b803'	System	17 Oct 2020 22:46:12
User entered '0'	System	17 Oct 2020 22:46:12

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:46:07', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8a9274b2-fad8-4cee-9856-efbc11d9b803'	System	17 Oct 2020 22:46:12
User entered '17 Oct 2020 18:46'	System	17 Oct 2020 22:46:12

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 6'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:01:24', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6635cafb-ce8d-42c2-ac44-39e9eefa0533'	System	18 Oct 2020 23:01:40
User entered 'Yes (Y)'	System	18 Oct 2020 23:01:40

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:01:27', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6635cafb-ce8d-42c2-ac44-39e9eefa0533'	System	18 Oct 2020 23:01:40
User entered '98.5'	System	18 Oct 2020 23:01:40

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:01:33', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6635cafb-ce8d-42c2-ac44-39e9eefa0533'	System	18 Oct 2020 23:01:40
User entered 'No (N)'	System	18 Oct 2020 23:01:40

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:01:35', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6635cafb-ce8d-42c2-ac44-39e9eefa0533'	System	18 Oct 2020 23:01:40
User entered '18 Oct 2020 19:01'	System	18 Oct 2020 23:01:40

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 7'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:44:48', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0a078a11-8b43-4029-b8e1-ea3617f0104e'	System	20 Oct 2020 00:45:05
User entered 'Yes (Y)'	System	20 Oct 2020 00:45:05

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:44:52', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0a078a11-8b43-4029-b8e1-ea3617f0104e'	System	20 Oct 2020 00:45:05
User entered '98.3'	System	20 Oct 2020 00:45:05

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:44:57', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0a078a11-8b43-4029-b8e1-ea3617f0104e'	System	20 Oct 2020 00:45:05
User entered 'No (N)'	System	20 Oct 2020 00:45:05

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:44:59', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0a078a11-8b43-4029-b8e1-ea3617f0104e'	System	20 Oct 2020 00:45:05
User entered '19 Oct 2020 20:44'	System	20 Oct 2020 00:45:05

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:34', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0c327097-7f5f-48e5-ac9a-bc4eae0d6f6b'	System	13 Oct 2020 13:00:50
User entered 'None (1)'	System	13 Oct 2020 13:00:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:36', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0c327097-7f5f-48e5-ac9a-bc4eae0d6f6b'	System	13 Oct 2020 13:00:50
User entered 'No (N)'	System	13 Oct 2020 13:00:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:38', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0c327097-7f5f-48e5-ac9a-bc4eae0d6f6b'	System	13 Oct 2020 13:00:50
User entered 'No (N)'	System	13 Oct 2020 13:00:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:40', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0c327097-7f5f-48e5-ac9a-bc4eae0d6f6b'	System	13 Oct 2020 13:00:50
User entered 'None (1)'	System	13 Oct 2020 13:00:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:42', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0c327097-7f5f-48e5-ac9a-bc4eae0d6f6b'	System	13 Oct 2020 13:00:50
User entered '13 Oct 2020 09:00'	System	13 Oct 2020 13:00:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 08:39'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:09'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:09', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e3b38d89-068b-4304-984e-a386a356b9f7'	System	14 Oct 2020 12:44:25
User entered 'None (1)'	System	14 Oct 2020 12:44:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:11', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e3b38d89-068b-4304-984e-a386a356b9f7'	System	14 Oct 2020 12:44:25
User entered 'No (N)'	System	14 Oct 2020 12:44:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:13', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e3b38d89-068b-4304-984e-a386a356b9f7'	System	14 Oct 2020 12:44:25
User entered 'No (N)'	System	14 Oct 2020 12:44:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:15', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e3b38d89-068b-4304-984e-a386a356b9f7'	System	14 Oct 2020 12:44:25
User entered 'None (1)'	System	14 Oct 2020 12:44:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:17', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e3b38d89-068b-4304-984e-a386a356b9f7'	System	14 Oct 2020 12:44:25
User entered '14 Oct 2020 08:44'	System	14 Oct 2020 12:44:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:04'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 2'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-15T07:15:06', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '07357dab-e231-446b-b00c-65b858e29fd8'	System	15 Oct 2020 13:46:50
User entered 'None (1)'	System	15 Oct 2020 13:46:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T07:15:09', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '07357dab-e231-446b-b00c-65b858e29fd8'	System	15 Oct 2020 13:46:50
User entered 'No (N)'	System	15 Oct 2020 13:46:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T07:15:13', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '07357dab-e231-446b-b00c-65b858e29fd8'	System	15 Oct 2020 13:46:50
User entered 'No (N)'	System	15 Oct 2020 13:46:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-15T09:46:41', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '07357dab-e231-446b-b00c-65b858e29fd8'	System	15 Oct 2020 13:46:50
User entered 'None (1)'	System	15 Oct 2020 13:46:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T09:46:46', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '07357dab-e231-446b-b00c-65b858e29fd8'	System	15 Oct 2020 13:46:50
User entered '15 Oct 2020 09:46'	System	15 Oct 2020 13:46:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 3'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:28', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6777735a-afc9-41c4-8973-3d16ee13c1a9'	System	15 Oct 2020 19:57:44
User entered 'None (1)'	System	15 Oct 2020 19:57:44

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:31', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6777735a-afc9-41c4-8973-3d16ee13c1a9'	System	15 Oct 2020 19:57:44
User entered 'No (N)'	System	15 Oct 2020 19:57:44

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:33', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6777735a-afc9-41c4-8973-3d16ee13c1a9'	System	15 Oct 2020 19:57:44
User entered 'No (N)'	System	15 Oct 2020 19:57:44

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:35', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6777735a-afc9-41c4-8973-3d16ee13c1a9'	System	15 Oct 2020 19:57:44
User entered 'None (1)'	System	15 Oct 2020 19:57:44

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:40', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6777735a-afc9-41c4-8973-3d16ee13c1a9'	System	15 Oct 2020 19:57:44
User entered '15 Oct 2020 15:57'	System	15 Oct 2020 19:57:44

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 4'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-16T19:21:55', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '863914a6-4a6c-4c03-b2cc-00bb9ffa9a8f'	System	16 Oct 2020 23:22:18
User entered 'None (1)'	System	16 Oct 2020 23:22:18

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:21:59', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '863914a6-4a6c-4c03-b2cc-00bb9ffa9a8f'	System	16 Oct 2020 23:22:18
User entered 'No (N)'	System	16 Oct 2020 23:22:18

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:01', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '863914a6-4a6c-4c03-b2cc-00bb9ffa9a8f'	System	16 Oct 2020 23:22:18
User entered 'No (N)'	System	16 Oct 2020 23:22:18

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:09', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '863914a6-4a6c-4c03-b2cc-00bb9ffa9a8f'	System	16 Oct 2020 23:22:18
User entered 'None (1)'	System	16 Oct 2020 23:22:18

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:13', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '863914a6-4a6c-4c03-b2cc-00bb9ffa9a8f'	System	16 Oct 2020 23:22:18
User entered '16 Oct 2020 19:22'	System	16 Oct 2020 23:22:18

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 5'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-17T18:46:11', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6bda3299-2cee-4d81-a652-014c3d0117d0'	System	17 Oct 2020 22:46:25
User entered 'None (1)'	System	17 Oct 2020 22:46:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:46:13', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6bda3299-2cee-4d81-a652-014c3d0117d0'	System	17 Oct 2020 22:46:25
User entered 'No (N)'	System	17 Oct 2020 22:46:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:46:15', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6bda3299-2cee-4d81-a652-014c3d0117d0'	System	17 Oct 2020 22:46:25
User entered 'No (N)'	System	17 Oct 2020 22:46:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-17T18:46:18', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6bda3299-2cee-4d81-a652-014c3d0117d0'	System	17 Oct 2020 22:46:25
User entered 'None (1)'	System	17 Oct 2020 22:46:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:46:21', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6bda3299-2cee-4d81-a652-014c3d0117d0'	System	17 Oct 2020 22:46:25
User entered '17 Oct 2020 18:46'	System	17 Oct 2020 22:46:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 6'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-18T19:01:50', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fba59ceb-c74f-4f3e-9323-fb593943de2e'	System	18 Oct 2020 23:02:20
User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 23:02:20

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:05', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fba59ceb-c74f-4f3e-9323-fb593943de2e'	System	18 Oct 2020 23:02:20
User entered 'No (N)'	System	18 Oct 2020 23:02:20

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:08', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fba59ceb-c74f-4f3e-9323-fb593943de2e'	System	18 Oct 2020 23:02:20
User entered 'No (N)'	System	18 Oct 2020 23:02:20

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:13', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fba59ceb-c74f-4f3e-9323-fb593943de2e'	System	18 Oct 2020 23:02:20
User entered 'None (1)'	System	18 Oct 2020 23:02:20

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:16', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fba59ceb-c74f-4f3e-9323-fb593943de2e'	System	18 Oct 2020 23:02:20
User entered '18 Oct 2020 19:02'	System	18 Oct 2020 23:02:20

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 7'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:03', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1fd36ea6-ce06-4e3b-be9f-1b595eb05afa'	System	20 Oct 2020 00:45:26
User entered 'None (1)'	System	20 Oct 2020 00:45:26

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:11', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1fd36ea6-ce06-4e3b-be9f-1b595eb05afa'	System	20 Oct 2020 00:45:26
User entered 'No (N)'	System	20 Oct 2020 00:45:26

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:15', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1fd36ea6-ce06-4e3b-be9f-1b595eb05afa'	System	20 Oct 2020 00:45:26
User entered 'No (N)'	System	20 Oct 2020 00:45:26

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:19', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1fd36ea6-ce06-4e3b-be9f-1b595eb05afa'	System	20 Oct 2020 00:45:26
User entered 'None (1)'	System	20 Oct 2020 00:45:26

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:21', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1fd36ea6-ce06-4e3b-be9f-1b595eb05afa'	System	20 Oct 2020 00:45:26
User entered '19 Oct 2020 20:45'	System	20 Oct 2020 00:45:26

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:52', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b03ce50c-3fd6-4bc0-8de4-d592ac42593a'	System	13 Oct 2020 13:01:12
User entered 'No interference with activity (1)'	System	13 Oct 2020 13:01:12

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:54', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b03ce50c-3fd6-4bc0-8de4-d592ac42593a'	System	13 Oct 2020 13:01:12
User entered 'None (0)'	System	13 Oct 2020 13:01:12

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:56', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b03ce50c-3fd6-4bc0-8de4-d592ac42593a'	System	13 Oct 2020 13:01:12
User entered 'None (0)'	System	13 Oct 2020 13:01:12

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:58', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b03ce50c-3fd6-4bc0-8de4-d592ac42593a'	System	13 Oct 2020 13:01:12
User entered 'None (0)'	System	13 Oct 2020 13:01:12

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:59', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b03ce50c-3fd6-4bc0-8de4-d592ac42593a'	System	13 Oct 2020 13:01:12
User entered 'None (0)'	System	13 Oct 2020 13:01:12

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:01:01', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b03ce50c-3fd6-4bc0-8de4-d592ac42593a'	System	13 Oct 2020 13:01:12
User entered 'None (0)'	System	13 Oct 2020 13:01:12

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-13T09:01:05', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b03ce50c-3fd6-4bc0-8de4-d592ac42593a'	System	13 Oct 2020 13:01:12
User entered 'No (N)'	System	13 Oct 2020 13:01:12

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:01:07', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b03ce50c-3fd6-4bc0-8de4-d592ac42593a'	System	13 Oct 2020 13:01:12
User entered '13 Oct 2020 09:01'	System	13 Oct 2020 13:01:12

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 08:39'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:09'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:20', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'beae4f15-2603-4ebb-999d-f3ad1cbe048f'	System	14 Oct 2020 12:44:38
User entered 'No interference with activity (1)'	System	14 Oct 2020 12:44:38

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:22', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'beae4f15-2603-4ebb-999d-f3ad1cbe048f'	System	14 Oct 2020 12:44:38
User entered 'None (0)'	System	14 Oct 2020 12:44:38

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:23', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'beae4f15-2603-4ebb-999d-f3ad1cbe048f' User entered 'None (0)'	System	14 Oct 2020 12:44:38

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:25', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'beae4f15-2603-4ebb-999d-f3ad1cbe048f' User entered 'None (0)'	System	14 Oct 2020 12:44:38

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:26', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'beae4f15-2603-4ebb-999d-f3ad1cbe048f' User entered 'None (0)'	System	14 Oct 2020 12:44:38

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:28', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'beae4f15-2603-4ebb-999d-f3ad1cbe048f'	System	14 Oct 2020 12:44:38
User entered 'None (0)'	System	14 Oct 2020 12:44:38

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:30', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'beae4f15-2603-4ebb-999d-f3ad1cbe048f'	System	14 Oct 2020 12:44:38
User entered 'No (N)'	System	14 Oct 2020 12:44:38

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:31', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'beae4f15-2603-4ebb-999d-f3ad1cbe048f' User entered '14 Oct 2020 08:44'	System	14 Oct 2020 12:44:38
	System	14 Oct 2020 12:44:38

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:04'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 2'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T09:46:49', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1392b7f6-23f2-4faa-bfe0-c10bd34efee1'	System	15 Oct 2020 13:47:16
User entered 'None (0)'	System	15 Oct 2020 13:47:16

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T09:46:51', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1392b7f6-23f2-4faa-bfe0-c10bd34efee1'	System	15 Oct 2020 13:47:16
User entered 'None (0)'	System	15 Oct 2020 13:47:16

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T09:46:54', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1392b7f6-23f2-4faa-bfe0-c10bd34efee1'	System	15 Oct 2020 13:47:16
User entered 'None (0)'	System	15 Oct 2020 13:47:16

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T09:46:56', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1392b7f6-23f2-4faa-bfe0-c10bd34efee1'	System	15 Oct 2020 13:47:16
User entered 'None (0)'	System	15 Oct 2020 13:47:16

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T09:47:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1392b7f6-23f2-4faa-bfe0-c10bd34efee1'	System	15 Oct 2020 13:47:16
User entered 'None (0)'	System	15 Oct 2020 13:47:16

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T09:47:02', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1392b7f6-23f2-4faa-bfe0-c10bd34efee1'	System	15 Oct 2020 13:47:16
User entered 'None (0)'	System	15 Oct 2020 13:47:16

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-15T09:47:05', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1392b7f6-23f2-4faa-bfe0-c10bd34efee1'	System	15 Oct 2020 13:47:16
User entered 'No (N)'	System	15 Oct 2020 13:47:16

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T09:47:09', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1392b7f6-23f2-4faa-bfe0-c10bd34efee1'	System	15 Oct 2020 13:47:16
User entered '15 Oct 2020 09:47'	System	15 Oct 2020 13:47:16

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 3'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:43', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '3af31c6b-ddde-4346-ad17-d183dbf61f03'	System	15 Oct 2020 19:58:01
User entered 'None (0)'	System	15 Oct 2020 19:58:01

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:44', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '3af31c6b-ddde-4346-ad17-d183dbf61f03'	System	15 Oct 2020 19:58:01
User entered 'None (0)'	System	15 Oct 2020 19:58:01

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:46', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '3af31c6b-ddde-4346-ad17-d183dbf61f03'	System	15 Oct 2020 19:58:01
User entered 'None (0)'	System	15 Oct 2020 19:58:01

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:48', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '3af31c6b-ddde-4346-ad17-d183dbf61f03'	System	15 Oct 2020 19:58:01
User entered 'None (0)'	System	15 Oct 2020 19:58:01

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:49', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '3af31c6b-ddde-4346-ad17-d183dbf61f03'	System	15 Oct 2020 19:58:01
User entered 'None (0)'	System	15 Oct 2020 19:58:01

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:51', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '3af31c6b-ddde-4346-ad17-d183dbf61f03'	System	15 Oct 2020 19:58:01
User entered 'None (0)'	System	15 Oct 2020 19:58:01

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:53', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '3af31c6b-ddde-4346-ad17-d183dbf61f03'	System	15 Oct 2020 19:58:01
User entered 'No (N)'	System	15 Oct 2020 19:58:01

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:57', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '3af31c6b-ddde-4346-ad17-d183dbf61f03'	System	15 Oct 2020 19:58:01
User entered '15 Oct 2020 15:57'	System	15 Oct 2020 19:58:01

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 4'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:26', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a6347815-f663-447c-acd1-438676e530f0'	System	16 Oct 2020 23:22:41
User entered 'No interference with activity (1)'	System	16 Oct 2020 23:22:41

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:21', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a6347815-f663-447c-acd1-438676e530f0'	System	16 Oct 2020 23:22:41
User entered 'None (0)'	System	16 Oct 2020 23:22:41

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:20', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a6347815-f663-447c-acd1-438676e530f0'	System	16 Oct 2020 23:22:41
User entered 'None (0)'	System	16 Oct 2020 23:22:41

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:28', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a6347815-f663-447c-acd1-438676e530f0'	System	16 Oct 2020 23:22:41
User entered 'None (0)'	System	16 Oct 2020 23:22:41

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:29', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a6347815-f663-447c-acd1-438676e530f0'	System	16 Oct 2020 23:22:41
User entered 'None (0)'	System	16 Oct 2020 23:22:41

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:31', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a6347815-f663-447c-acd1-438676e530f0'	System	16 Oct 2020 23:22:41
User entered 'None (0)'	System	16 Oct 2020 23:22:41

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:35', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a6347815-f663-447c-acd1-438676e530f0'	System	16 Oct 2020 23:22:41
User entered 'No (N)'	System	16 Oct 2020 23:22:41

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:37', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a6347815-f663-447c-acd1-438676e530f0'	System	16 Oct 2020 23:22:41
User entered '16 Oct 2020 19:22'	System	16 Oct 2020 23:22:41

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 5'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:47:11', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ff3f2ca-0ae5-4481-9229-af62914fca06'	System	17 Oct 2020 22:47:36
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	17 Oct 2020 22:47:36

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:47:14', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ff3f2ca-0ae5-4481-9229-af62914fca06'	System	17 Oct 2020 22:47:36
User entered 'None (0)'	System	17 Oct 2020 22:47:36

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:47:16', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ff3f2ca-0ae5-4481-9229-af62914fca06'	System	17 Oct 2020 22:47:36
User entered 'None (0)'	System	17 Oct 2020 22:47:36

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:47:18', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ff3f2ca-0ae5-4481-9229-af62914fca06'	System	17 Oct 2020 22:47:36
User entered 'None (0)'	System	17 Oct 2020 22:47:36

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:47:22', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ff3f2ca-0ae5-4481-9229-af62914fca06'	System	17 Oct 2020 22:47:36
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	17 Oct 2020 22:47:36

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:47:24', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ff3f2ca-0ae5-4481-9229-af62914fca06'	System	17 Oct 2020 22:47:36
User entered 'None (0)'	System	17 Oct 2020 22:47:36

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-17T18:47:28', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ff3f2ca-0ae5-4481-9229-af62914fca06'	System	17 Oct 2020 22:47:36
User entered 'No (N)'	System	17 Oct 2020 22:47:36

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:47:32', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ff3f2ca-0ae5-4481-9229-af62914fca06'	System	17 Oct 2020 22:47:36
User entered '17 Oct 2020 18:47'	System	17 Oct 2020 22:47:36

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 6'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:21', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a87627ac-552f-47ac-8e08-84004763a99c'	System	18 Oct 2020 23:02:40
User entered 'None (0)'	System	18 Oct 2020 23:02:40

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:22', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a87627ac-552f-47ac-8e08-84004763a99c'	System	18 Oct 2020 23:02:40
User entered 'None (0)'	System	18 Oct 2020 23:02:40

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:24', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a87627ac-552f-47ac-8e08-84004763a99c'	System	18 Oct 2020 23:02:40
User entered 'None (0)'	System	18 Oct 2020 23:02:40

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:26', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a87627ac-552f-47ac-8e08-84004763a99c'	System	18 Oct 2020 23:02:40
User entered 'None (0)'	System	18 Oct 2020 23:02:40

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:27', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a87627ac-552f-47ac-8e08-84004763a99c'	System	18 Oct 2020 23:02:40
User entered 'None (0)'	System	18 Oct 2020 23:02:40

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:28', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a87627ac-552f-47ac-8e08-84004763a99c'	System	18 Oct 2020 23:02:40
User entered 'None (0)'	System	18 Oct 2020 23:02:40

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:32', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a87627ac-552f-47ac-8e08-84004763a99c'	System	18 Oct 2020 23:02:40
User entered 'No (N)'	System	18 Oct 2020 23:02:40

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:34', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a87627ac-552f-47ac-8e08-84004763a99c'	System	18 Oct 2020 23:02:40
User entered '18 Oct 2020 19:02'	System	18 Oct 2020 23:02:40

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 7'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:25', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c01beb63-0fce-4cd3-969d-93b64170701b'	System	20 Oct 2020 00:45:56
User entered 'None (0)'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:28', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c01beb63-0fce-4cd3-969d-93b64170701b'	System	20 Oct 2020 00:45:56
User entered 'No interference with activity (1)'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:31', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c01beb63-0fce-4cd3-969d-93b64170701b'	System	20 Oct 2020 00:45:56
User entered 'No interference with activity (1)'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:36', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c01beb63-0fce-4cd3-969d-93b64170701b'	System	20 Oct 2020 00:45:56
User entered 'None (0)'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:39', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c01beb63-0fce-4cd3-969d-93b64170701b'	System	20 Oct 2020 00:45:56
User entered 'None (0)'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:40', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c01beb63-0fce-4cd3-969d-93b64170701b'	System	20 Oct 2020 00:45:56
User entered 'None (0)'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:43', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c01beb63-0fce-4cd3-969d-93b64170701b'	System	20 Oct 2020 00:45:56
User entered 'No (N)'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:51', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c01beb63-0fce-4cd3-969d-93b64170701b'	System	20 Oct 2020 00:45:56
User entered '19 Oct 2020 20:45'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 00:45:56
User entered 'Day 8'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:14:07

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-20T12:19:22', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '99d85670-df51-481b-a8ff-1c5d45742e17'	System	20 Oct 2020 16:19:29
User entered 'None (0)'	System	20 Oct 2020 16:19:29

US3742384

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:14:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-20T12:19:25', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '99d85670-df51-481b-a8ff-1c5d45742e17'	System	20 Oct 2020 16:19:29
User entered '20 Oct 2020 12:19'	System	20 Oct 2020 16:19:29

US3742384

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 00:45:56
User entered 'Day 8'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:14:07

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-20T12:19:28', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e0ea8a3e-dd40-430d-8911-d158625d8717'	System	20 Oct 2020 16:19:34
User entered 'None (0)'	System	20 Oct 2020 16:19:34

US3742384

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:14:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-20T12:19:30', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e0ea8a3e-dd40-430d-8911-d158625d8717'	System	20 Oct 2020 16:19:34
User entered '20 Oct 2020 12:19'	System	20 Oct 2020 16:19:34

US3742384

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	20 Oct 2020 00:45:56
DataPoint Inactivated.	System	20 Oct 2020 00:45:26
Data entry locked.	System	18 Oct 2020 23:02:20
User entered 'Day 8'	System	18 Oct 2020 23:02:20

US3742384

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-10-20T12:19:36', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b676e880-83bb-45e8-9e00-8f99e95c8083'	System	20 Oct 2020 16:19:49
User entered 'No (N)'	System	20 Oct 2020 16:19:49
DataPoint Activated.	System	20 Oct 2020 00:45:56
DataPoint Inactivated.	System	20 Oct 2020 00:45:26

US3742384

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:14:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-20T12:19:41', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b676e880-83bb-45e8-9e00-8f99e95c8083'	System	20 Oct 2020 16:19:49
User entered '20 Oct 2020 12:19'	System	20 Oct 2020 16:19:49
DataPoint Activated.	System	20 Oct 2020 00:45:56
DataPoint Inactivated.	System	20 Oct 2020 00:45:26

US3742384

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:14:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	20 Oct 2020 00:45:56
DataPoint Inactivated.	System	20 Oct 2020 00:45:26
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 23:02:20

US3742384

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:14:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	20 Oct 2020 00:45:56
DataPoint Inactivated.	System	20 Oct 2020 00:45:26
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 23:02:20

US3742384

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:40:13

US3742384

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:40:13

US3742384

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:40:13

US3742384

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:40:13

US3742384

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:40:21

US3742384

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 17:40:21

US3742384

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 13:10:25

US3742384

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 13:10:25

US3742384

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Oct 2020 13:10:25

US3742384

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 13:10:25

US3742384

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 13:10:31

US3742384

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 13:10:31

US3742384

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	03 Nov 2020 18:43:10
	(b) (4)	

US3742384

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '3 Nov 2020'	Sherry McCammon (b) (4)	03 Nov 2020 18:43:10
	(b) (4)	

US3742384

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	03 Nov 2020 18:43:10

US3742384

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	03 Nov 2020 18:43:10
	(b) (4)	

US3742384

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	03 Nov 2020 18:43:16
	(b) (4)	

US3742384

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 18:43:16

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 64'	System	16 Sep 2020 14:06:16

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[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 (d06fb84cf1d8da2d)', Time: '2020-11-16T08:40:01', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4a0ca7f8-a9f0-4ed3-aabe-e78fd1c55303'	System	16 Nov 2020 13:40:52
User entered 'Yes (Y)'	System	16 Nov 2020 13:40:52

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2020-11-16T08:40:07', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4a0ca7f8-a9f0-4ed3-aabe-e78fd1c55303'	System	16 Nov 2020 13:40:52
User entered 'No (N)'	System	16 Nov 2020 13:40:52

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-11-16T08:40:13', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4a0ca7f8-a9f0-4ed3-aabe-e78fd1c55303'	System	16 Nov 2020 13:40:52
User entered 'No (N)'	System	16 Nov 2020 13:40:52

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-11-16T08:40:20', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4a0ca7f8-a9f0-4ed3-aabe-e78fd1c55303'	System	16 Nov 2020 13:40:52
User entered 'Yes (Y)'	System	16 Nov 2020 13:40:52

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-11-16T08:40:26', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4a0ca7f8-a9f0-4ed3-aabe-e78fd1c55303'	System	16 Nov 2020 13:40:52
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Nov 2020 13:40:52

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-11-16T08:40:34', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4a0ca7f8-a9f0-4ed3-aabe-e78fd1c55303'	System	16 Nov 2020 13:40:52
User entered '16 Nov 2020 08:40:34'	System	16 Nov 2020 13:40:52

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered '16 Nov 2020 00:01'	System	16 Sep 2020 14:06:16

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:06:16
User entered '20 Nov 2020 23:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '13 Nov 2020 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '17 Nov 2020 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

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 (d06fb84cf1d8da2d)', Time: '2020-11-20T15:10:25', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '27bf21fe-49b3-4d35-8175-52b49fb678c5'	System	20 Nov 2020 20:10:34
User entered 'No (N)'	System	20 Nov 2020 20:10:34

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2020-11-20T15:10:20', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '27bf21fe-49b3-4d35-8175-52b49fb678c5'	System	20 Nov 2020 20:10:34
User entered 'No (N)'	System	20 Nov 2020 20:10:34

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-11-20T15:10:27', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '27bf21fe-49b3-4d35-8175-52b49fb678c5'	System	20 Nov 2020 20:10:34
User entered '20 Nov 2020 15:10:27'	System	20 Nov 2020 20:10:34

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:14:07

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:52:15
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:34:35

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Bacterial vaginosis, LLT: Bacterial vaginosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 17:38:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 17:38:23
Data point term sent to Coder	System	13 Oct 2020 17:37:07
User entered 'bacterial vaginosis'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '7 Oct 2020'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)' reason for change: New Information	Kaitlin Mason (b) (4)	20 Oct 2020 17:38:13
User entered 'Yes (Y)'	(b) (4)	
	Hassan Haji (b) (4)	13 Oct 2020 17:36:22
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '15 Oct 2020' reason for change: New Information	Kaitlin Mason (b) (4)	20 Oct 2020 17:38:13
User entered empty.	(b) (4)	
	Hassan Haji (b) (4)	13 Oct 2020 17:36:22
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'None (NONE)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#7) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:45:19
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#7) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 21:25:24
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 21:25:00
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#7) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:37:44
User entered '1'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 21:25:00
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 17:38:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 17:38:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:38:13
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 17:36:22
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this Solicited Adverse Reaction as this has been recorded in the diary forms. Note that solicited reactions are only to reported as AE if it meets AE reporting criteria per protocol. Please review and remove if needed. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:08:29
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
Query 'Per DM CLR: Please review this Solicited Adverse Reaction as this has been recorded in the diary forms. Note that solicited reactions are only to reported as AE if it meets AE reporting criteria per protocol. Please review and remove if needed. Else, clarify.' answered with 'This is an AE due to the headache occurring prior to vaccination #2.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:35:49
User opened query 'Per DM CLR: Please review this Solicited Adverse Reaction as this has been recorded in the diary forms. Note that solicited reactions are only to reported as AE if it meets AE reporting criteria per protocol. Please review and remove if needed. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:37:58
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 17:39:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 17:39:26
Data point term sent to Coder	System	13 Oct 2020 17:38:08
User entered 'headache'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '13 Oct 2020'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '05:00'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 05:00'	System	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '13 Oct 2020'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '08:00'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 08:00'	System	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'Grade 1/Mild (Grade 1/Mild)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'None (NONE)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#11) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:08:36
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#11) recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4)	18 Nov 2020 14:37:45
User entered '0' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 14:37:40
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#11) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:38:04
User entered '1'	Hassan Haji (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	18 Nov 2020 14:37:40
User entered '0'	Hassan Haji (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 17:37:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 17:37:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:42
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 17:37:34
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:27
User entered 'USA-US127-2020-mRNA-1273-P301000008'	System	04 Nov 2020 15:47:21
User entered 'New'	(b) (4), (b) (6)	04 Nov 2020 15:47:21

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 18:51:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 18:51:24
Data point term sent to Coder	System	03 Nov 2020 18:50:59
User entered 'DIVERTICULITIS'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'No (N)'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '01 Nov 2020'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered empty.	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 18:50:58

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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)	19 Nov 2020 17:51:19
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 'Participant is recovering ' (Site from Safety).	Kaitlin Mason (b) (4)	18 Nov 2020 14:42:18
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)	12 Nov 2020 18:36:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered empty.	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered empty.	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 18:50:58

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '0'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '0'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'per CDM RQ: please respond to this query when data is entered' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:00:49
Query 'per CDM RQ: please respond to this query when data is entered' answered with 'safety report form has been entered' (Site from DM).	Kaitlin Mason (b) (4)	19 Nov 2020 19:00:14
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 17:12:13
User opened query 'per CDM RQ: please respond to this query when data is entered' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:12:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Event is ongoing; participant is currently hospitalized so no discharge date available.' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 19:28:59
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	03 Nov 2020 18:50:58
User entered '1'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '01 Nov 2020'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
DataPoint Un-verified.	Sherry McCammon (b) (4)	10 Nov 2020 20:00:49
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 20:00:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered empty.	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	03 Nov 2020 19:29:32
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		03 Nov 2020 19:29:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 19:29:32
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	03 Nov 2020 18:55:23
User entered 'Unknown (UNK)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	03 Nov 2020 18:55:23
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4)	03 Nov 2020 18:51:34
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	03 Nov 2020 18:51:34
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	03 Nov 2020 18:51:34
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4)	03 Nov 2020 18:50:58
User entered 'Unknown (UNK)'	System	03 Nov 2020 18:50:58
	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered empty.	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '0'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '0'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '0'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'Not Applicable (NOT APPLICABLE)'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
DataPoint Un-verified.	Sherry McCammon (b) (4)	10 Nov 2020 19:55:19
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	10 Nov 2020 19:55:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '1'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
DataPoint Un-verified.	Sherry McCammon (b) (4)	10 Nov 2020 19:55:19
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	10 Nov 2020 19:55:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '0'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '0'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Outcome](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:51:28
	(b) (4), (b) (6)	18 Nov 2020 20:33:41
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 'Participant was discharged Nov 9 2020 but is still experiencing ongoing recovery ' (Site from Safety).	Kaitlin Mason (b) (4)	18 Nov 2020 14:41:58
	(b) (4)	
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). DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 18:35:06
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error DataPoint Verified.	Sherry McCammon (b) (4)	10 Nov 2020 19:53:43
	(b) (4)	
	Sherry McCammon (b) (4)	10 Nov 2020 19:53:43
	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 19:29:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 19:29:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 19:29:32
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 18:50:58
User entered empty.	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered empty.	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:05:36
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 17:52:12
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 17:52:05
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Participant was hospitalized for over a week. Please specify labs requested if desired.' (Site from Safety).	Kaitlin Mason (b) (4)	18 Nov 2020 14:46:02
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Medications were added to conmeds and entered into SAE report ' (Site from Safety).	Kaitlin Mason (b) (4)	18 Nov 2020 14:40:42
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'SARS-CoV-2 Genexpert testing conducted November 1st and was not detected ' (Site from Safety).	Kaitlin Mason (b) (4)	18 Nov 2020 14:40:20

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 18:35:53
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 18:34:55
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 18:34:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Nov 2020 18:54:18
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	03 Nov 2020 18:54:18
User entered 'VOLUNTEER REPORTS BEING HOSPITALIZED FOR DIVERTICULITIS. SAE REPORTED.' reason for change: Data Entry Error	Sherry McCammon (b) (4)	03 Nov 2020 18:54:18
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Nov 2020 18:50:58
User entered empty.	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 18:50:58

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 18:50:58

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '0'	System	03 Nov 2020 18:50:58

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:14:07

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:46:58

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: VARENICLINE TARTRATE, PRODUCTSYNONYM: CHANTIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 14:50:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 14:50:38
Data point term sent to Coder	System	16 Sep 2020 14:49:25
User entered 'chantix'	Hassan Haji (b) (4)	16 Sep 2020 14:48:39
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 16:34:38
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' answered with 'no medical condition.' (Site from DM).	Sherry McCammon (b) (4)	10 Nov 2020 19:41:54
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:58:31
User entered 'smoking cessation'	Hassan Haji (b) (4)	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '12 Dec 2016'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:52:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:52:40
Data point term sent to Coder	System	16 Sep 2020 14:51:32
User entered 'hydrochlorothiazide'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '12.5'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '30 Jun 2017'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:54:38
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 Sep 2020 14:54:38
Data point term sent to Coder	System	16 Sep 2020 14:53:38
User entered 'losartan'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '30 Jun 2017'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 14:59:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 14:59:43
Data point term sent to Coder	System	16 Sep 2020 14:58:48
User entered 'prednisone'	Hassan Haji (b) (4)	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'sarcoidosis'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

[Dose per administration](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered, as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:01:38
User opened query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered, as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:59:32
User entered '5'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'UN Jul 2019'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 15:00:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 15:00:44
Data point term sent to Coder	System	16 Sep 2020 14:59:53
User entered 'trelegy ellipta'	Hassan Haji (b) (4)	16 Sep 2020 14:59:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'sarcoidosis'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100-62.5'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 17:55:04
Query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' answered with 'ENTERED IN ERROR' (Site from DM).	Kaitlin Mason (b) (4)	06 Oct 2020 19:55:17
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	06 Oct 2020 19:55:11
User opened query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 16:29:50
User entered 'Other (OTHER)'	Hassan Haji (b) (4)	16 Sep 2020 14:59:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	06 Oct 2020 19:55:11
User entered 'mcg'	Hassan Haji (b) (4)	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: OTHER MINERAL PRODUCTS, PRODUCT: CHROMIUM NICOTINATE;NICOTINIC ACID, PRODUCTSYNONYM: CHROMEMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 02:59:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 02:59:00
Data point term sent to Coder Coding entries removed.	System Hassan Haji (b) (4) (b) (4)	23 Oct 2020 18:58:09 23 Oct 2020 18:57:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: OTHER MINERAL PRODUCTS, PRODUCT: CHROMIUM NICOTINATE;NICOTINIC ACID, PRODUCTSYNONYM: CHROMEMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 10:32:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 10:32:55
Data point term sent to Coder User entered 'chrommate'	System Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:04:02 16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Prophylaxis is No, however; indication recorded suggests medication was given as a prophylaxis. Please review and update as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 14:46:19
Query 'Per CDM: Prophylaxis is No, however; indication recorded suggests medication was given as a prophylaxis. Please review and update as appropriate or clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 15:40:12
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Oct 2020 15:40:01
User opened query 'Per CDM: Prophylaxis is No, however; indication recorded suggests medication was given as a prophylaxis. Please review and update as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:56:01
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'SUPPLEMENT prophylaxis' reason for change: Data Entry Error	Hassan Haji (b) (4)	23 Oct 2020 18:57:41
User entered 'supplement'	Hassan Haji (b) (4)	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered 'UN Jan 2018'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 17:27:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 17:27:46
Data point term sent to Coder	System	20 Oct 2020 17:26:37
User entered 'METRONIDAZOLE'	Kaitlin Mason (b) (4)	20 Oct 2020 17:26:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'BACTERIAL VAGINOSIS'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '08 Oct 2020'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:22:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:22:25
Data point term sent to Coder	System	20 Oct 2020 17:28:41
User entered 'B12 INJECTION'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'WEIGHT LOSS'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'every week (QS)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 17:28:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 17:28:21
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:21
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 17:28:16
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: BILE AND LIVER THERAPY, ATC: LIVER THERAPY, LIPOTROPICS, ATC: LIVER THERAPY, PRODUCT: CHOLINE;INOSITOL;METHIONINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:06:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:06:31
Data point term sent to Coder	System	20 Oct 2020 17:33:53
User entered 'LIPOTROPIC [METHIONINE/INOSITOL/CHOLINE]'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'WEIGHT LOSS'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'INJECTION'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE, PRODUCTSYNONYM: BC [ACETYLSALICYLIC ACID;CAFFEINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 09:52:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 09:52:27
Data point term sent to Coder	System	20 Oct 2020 17:36:00
User entered 'BC TAB [ASPIRIN/CAFFEINE]'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'HEADACHE'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '845/65'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 17:37:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 17:37:40
Data point term sent to Coder	System	20 Oct 2020 17:37:03
User entered 'IBUPROFEN'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'HEADACHE'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '400'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Oct 2020'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LOVENOX [LEVOFLOXACIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:10:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:10:32
Data point term sent to Coder	System	10 Nov 2020 19:46:36
User entered 'LOVENOX'	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	10 Nov 2020 19:45:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'THROMBUS PROPHYLAXIS'	Sherry McCammon (b) (4)	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Sherry McCammon (b) (4)	10 Nov 2020 19:45:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Sherry McCammon (b) (4)	10 Nov 2020 19:45:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:45:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	10 Nov 2020 19:45:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:45:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Subcutaneous (SUBCUTANEOUS)'	Sherry McCammon (b) (4)	10 Nov 2020 19:45:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:45:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '01 Nov 2020'	Sherry McCammon (b) (4)	10 Nov 2020 19:45:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	10 Nov 2020 19:45:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	10 Nov 2020 19:45:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:45:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Nov 2020 19:45:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:08:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:08:32
Data point term sent to Coder	System	10 Nov 2020 19:48:38
User entered 'KETOROLAC'	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'DIVERTICULITIS'	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '30'	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '02 Nov 2020'	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:57:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:57:15
Data point term sent to Coder	System	10 Nov 2020 19:49:39
User entered 'PIPERACILLIN TAZOBACTAM'	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'DIVERTICULITIS'	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '3.375'	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'g (g)'	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '01 Nov 2020'	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:00:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:00:39
Data point term sent to Coder	System	10 Nov 2020 19:50:41
User entered 'ONDANSEETRON'	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Nov 2020 19:50:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'NAUSEA'	Sherry McCammon (b) (4)	10 Nov 2020 19:50:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '4'	Sherry McCammon (b) (4)	10 Nov 2020 19:50:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Sherry McCammon (b) (4)	10 Nov 2020 19:50:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:50:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Sherry McCammon (b) (4)	10 Nov 2020 19:50:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:50:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	Sherry McCammon (b) (4)	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:50:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '01 Nov 2020'	Sherry McCammon (b) (4)	10 Nov 2020 19:50:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	10 Nov 2020 19:50:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	10 Nov 2020 19:50:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:50:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Nov 2020 19:50:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:07:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:07:39
Data point term sent to Coder	System	10 Nov 2020 19:51:42
User entered 'LABETALOL'	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Nov 2020 19:51:26
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'HYPERTENSION'	Sherry McCammon (b) (4)	10 Nov 2020 19:51:26
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Sherry McCammon (b) (4)	10 Nov 2020 19:51:26
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Sherry McCammon (b) (4)	10 Nov 2020 19:51:26
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:51:26
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Sherry McCammon (b) (4)	10 Nov 2020 19:51:26
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:51:26
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	Sherry McCammon (b) (4)	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:51:26
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '02 Nov 2020'	Sherry McCammon (b) (4)	10 Nov 2020 19:51:26
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	10 Nov 2020 19:51:26
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	10 Nov 2020 19:51:26
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:51:26
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Nov 2020 19:51:26
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 19:53:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 19:53:41
Data point term sent to Coder	System	10 Nov 2020 19:52:44
User entered 'INFLUENZA VACCINE'	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'INFLUENZA PROPHYLAXIS'	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

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

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:14:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:52:19

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'USA-US127-2020-MRNA-1273-P301000008'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Karen'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Kotloff'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '685 W. Baltimore Street, HSF 480'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Baltimore'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:54
User entered 'MD' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 18:03:18
Un-reviewed for Safety.	System	19 Nov 2020 18:06:04
DataPoint Un-verified.	System	19 Nov 2020 18:06:04
User entered empty.	System	19 Nov 2020 18:06:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:34:45
User entered 'Maryland'	Kaitlin Mason (b) (4)	18 Nov 2020 14:24:44
	(b) (4)	

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '21201'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:18:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
User entered 'US'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 18:06:04
User entered '2'	System	11 Nov 2020 22:18:39
User entered '1'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'USA-US127-2020-MRNA-1273-P301000008'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Karen'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Kotloff'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '685 W. Baltimore Street, HSF 480'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Baltimore'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:54
User entered 'MD' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 18:03:18
Un-reviewed for Safety.	System	19 Nov 2020 18:06:04
DataPoint Un-verified.	System	19 Nov 2020 18:06:04
User entered empty.	System	19 Nov 2020 18:06:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:34:45
User entered 'Maryland'	Kaitlin Mason (b) (4)	18 Nov 2020 14:24:44
	(b) (4)	

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '21201'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:18:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
User entered 'US'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 18:06:04
User entered '2'	System	11 Nov 2020 22:18:39
User entered '1'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:14:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
User entered '04/Nov/2020 10:48'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:14:07

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)	11 Nov 2020 22:18:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
User entered '1'	(b) (4), (b) (6)	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'USA-US127-2020-MRNA-1273-P301000008'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Karen'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Kotloff'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '685 W. Baltimore Street, HSF 480'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Baltimore'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:54
User entered 'MD' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 18:03:18
Un-reviewed for Safety.	System	19 Nov 2020 18:06:04
DataPoint Un-verified.	System	19 Nov 2020 18:06:04
User entered empty.	System	19 Nov 2020 18:06:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:34:45
User entered 'Maryland'	Kaitlin Mason (b) (4)	18 Nov 2020 14:24:44
	(b) (4)	

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '21201'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:18:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
User entered 'US'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 18:06:04
User entered '2'	System	11 Nov 2020 22:18:39
User entered '1'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:14:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:34:45
User entered '11/Nov/2020 22:18'	System	11 Nov 2020 22:18:39

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:14:07

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 18:05:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:34:45
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 22:18:39

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'USA-US127-2020-MRNA-1273-P301000008'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Karen'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Kotloff'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '685 W. Baltimore Street, HSF 480'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Baltimore'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:54
User entered 'MD' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 18:03:18
Un-reviewed for Safety.	System	19 Nov 2020 18:06:04
DataPoint Un-verified.	System	19 Nov 2020 18:06:04
User entered empty.	System	19 Nov 2020 18:06:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:34:45
User entered 'Maryland'	Kaitlin Mason (b) (4)	18 Nov 2020 14:24:44
	(b) (4)	

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '21201'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:18:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
User entered 'US'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 11:14:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 18:06:04
User entered '2'	System	11 Nov 2020 22:18:39
User entered '1'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:14:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:54
User entered '19/Nov/2020 18:06'	System	19 Nov 2020 18:06:04

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:14:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:54
User entered '1'	(b) (4), (b) (6)	19 Nov 2020 18:06:04