

US3802218 (Prod: UPMC University Center)

Generated By: (b) (6)

Generated On: 26 Nov 2020 17:01:20

All time stamps listed in this document are displayed in GMT

US3802218

Form: Participant Creation

Generated On: 26 Nov 2020 17:01:20

[Participant ID](#)

US3802218

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

US3802218

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3802218

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 17:01:20

Date of Birth (MMM yyyy)	(b) (6) 1956
Age	64
Age Units	YEARS
Age (Derived)	64
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3802218

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 17:01:20

Date of Informed Consent (<i>dd MMM yyyy</i>)	11 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

US3802218

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 17:01:20

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3802218

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 17:01:20

Were any significant conditions reported?

Yes ☒

No ☐

US3802218

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 17:01:20

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

US3802218

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 17:01:20

Condition	DUST ALLERGY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802218

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 17:01:20

Condition	HIATAL HERNIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802218

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 17:01:20

Condition	GENERALIZED RASH
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3802218

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 17:01:20

Condition	ENRIONMENTAL ALLERGIES
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802218

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 17:01:20

Condition	HYPERTENSION
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802218

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 17:01:20

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802218

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 17:01:20

Condition	ANXIETY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802218

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 17:01:20

Condition	ENLARGED PROSTATE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802218

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 17:01:20

Condition	HYPERTRIGLYCERIDES
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802218

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 17:01:20

Condition	HIGH CHOLOESTEROL
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:20 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 10:20
Height (<i>xxx.x</i>)	172 cm
Weight (<i>xxx.x</i>)	245 lb
BMI (<i>xxx.x</i>)	37.64320 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	96.8 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	INFRARED
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802218

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 17:01:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

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	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

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

US3802218

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3802218

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 17:01:20

What was the date of randomization? (dd MMM yyyy) 11 SEP 2020

What was the participant's randomization number? 146137

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 ☐

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 17:01:20

Height	172 cm
Weight	245.5 lb

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

Height	172 cm
Weight	245.5 lb
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 10:20
Temperature (xxx.x)	96.8 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	INFRARED
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

Height	172 cm
Weight	245.5 lb
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	11:21 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 11:21
Temperature (xxx.x)	97.1 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	INFRARED
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3802218

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 17:01:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

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)	11 SEP 2020
What was the treatment time? (00:00-23:59)	10:46 (24 HR)
Treatment Date and Time (derived)	11 SEP 2020 10:46
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

US3802218

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 17:01:20

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

11 SEP 2020

Collection time (*00:00-23:59*)

10:34 (24 HR)

Collection date and time (derived)

11 SEP 2020 10:34

US3802218

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 17:01:20

Collection date (<i>dd MMM yyyy</i>)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:29	11 SEP 2020 10:29
Nasopharyngeal Swab 2	No		

US3802218

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

11 SEP 2020 11:26

PC Open Date & Time

11 SEP 2020 11:06

PC Close Date & Time

11 SEP 2020 13:36

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

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 97.6 °F

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

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

PC Time Stamp	11 SEP 2020 22:55
PC Open Date & Time	11 SEP 2020 14:31
PC Close Date & Time	12 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 17:01:20

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 20:39

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 17:01:20

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 21:57

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 17:01:20

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

98.1 °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

14 SEP 2020 14:36

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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 SEP 2020 14:01

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 17:01:20

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 00:09

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 17:01:20

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 18:58

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

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

11 SEP 2020 11:27

PC Open Date & Time

11 SEP 2020 11:06

PC Close Date & Time

11 SEP 2020 13:36

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

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

11 SEP 2020 22:56

PC Open Date & Time

11 SEP 2020 14:31

PC Close Date & Time

12 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 17:01:20

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

12 SEP 2020 15:52

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

DAY 3

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 SEP 2020 17:10

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 17:01:20

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

14 SEP 2020 14:36

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 17:01:20

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

15 SEP 2020 14:01

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 17:01:20

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

16 SEP 2020 18:24

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 17:01:20

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

17 SEP 2020 18:59

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 11:27
PC Open Date & Time	11 SEP 2020 11:06
PC Close Date & Time	11 SEP 2020 13:36

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 22:57
PC Open Date & Time	11 SEP 2020 14:31
PC Close Date & Time	12 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

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 ☒

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

Yes ☐	
PC Time stamp	12 SEP 2020 15:52
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

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 ☒

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

Yes ☐	
PC Time stamp	13 SEP 2020 17:09
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

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 ☒

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

Yes ☐	
PC Time stamp	14 SEP 2020 14:37
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

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 ☒

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

Yes ☐	
PC Time stamp	15 SEP 2020 14:02
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

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 ☒

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

Yes ☐	
PC Time stamp	16 SEP 2020 18:25
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

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 ☒

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

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

US3802218

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 19 SEP 2020 03:16

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	19 SEP 2020 03:16
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3802218

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

If Contact Not Made, please provide Comments

PATIENT CONTACT
ATTEMPTED ON THREE
SEPARATE OCCASIONS.
PATIENT WAS UNABLE TO BE
REACHED.

US3802218

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802218

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

THREE ATTEMPTS

UNSUCCESSFUL

If Contact Not Made, please provide Comments

US3802218

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

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

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

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)	10:43 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 10:43
Temperature (xxx.x)	95.2 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	INFRARED
Pulse (xxx)	108 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

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)	11:44 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 11:44
Temperature (xxx.x)	96.8 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	INFRARED
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3802218

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 17:01:20

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.

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

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)	11:12 (24 HR)
Treatment Date and Time (derived)	13 OCT 2020 11:12
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

US3802218

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 17:01:20

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	13 OCT 2020
Collection time (<i>00:00-23:59</i>)	10:52 (24 HR)
Collection date and time (derived)	13 OCT 2020 10:52

US3802218

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 17:01:20

Collection date (<i>dd MMM yyyy</i>)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:48	13 OCT 2020 10:48
Nasopharyngeal Swab 2	No		

US3802218

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

13 OCT 2020 11:46

PC Open Date & Time

13 OCT 2020 11:32

PC Close Date & Time

13 OCT 2020 14:02

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

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 97.1 °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	13 OCT 2020 21:50
PC Open Date & Time	13 OCT 2020 14:57
PC Close Date & Time	14 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 17:01:20

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 15 OCT 2020 01:19

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 17:01:20

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

98.5 °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

15 OCT 2020 18:41

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 17:01:20

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 17:22

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 17:01:20

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

98.3 °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

18 OCT 2020 01:18

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 17:01:20

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 00:01

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 17:01:20

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 17:52

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

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 11:46

PC Open Date & Time

13 OCT 2020 11:32

PC Close Date & Time

13 OCT 2020 14:02

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

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

13 OCT 2020 21:49

PC Open Date & Time

13 OCT 2020 14:57

PC Close Date & Time

14 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

DAY 2

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 01:19

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 17:01:20

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 18:41

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 17:01:20

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 17:22

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 01:18

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 00:01

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 17:01:20

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 17:52

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 11:47
PC Open Date & Time	13 OCT 2020 11:32
PC Close Date & Time	13 OCT 2020 14:02

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 21:49
PC Open Date & Time	13 OCT 2020 14:57
PC Close Date & Time	14 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

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 ☒

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

Yes ☐	
PC Time stamp	15 OCT 2020 01:20
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

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 ☒

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

Yes ☐	
PC Time stamp	15 OCT 2020 18:42
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

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 ☒

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

Yes ☐	
PC Time stamp	16 OCT 2020 17:23
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

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 ☒

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

Yes ☐	
PC Time stamp	18 OCT 2020 01:19
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

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 ☒

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

Yes ☐	
PC Time stamp	19 OCT 2020 00:01
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

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 ☒

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

Yes ☐	
PC Time stamp	19 OCT 2020 17:53
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3802218

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

CONTACT ATTEMPTED ON

10/20,10/21,10/22.

If Contact Not Made, please provide Comments

US3802218

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

ATTEMPTED TO CONTACT
PARTICIPANT 3 TIMES
WITHOUT SUCCESS

If Contact Not Made, please provide Comments

US3802218

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802218

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

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

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	12 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	10:10 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 10:10
Temperature (<i>xxx.x</i>)	97.3 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	INFRARED
Pulse (<i>xxx</i>)	89 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802218

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 17:01:20

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.

US3802218

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 17:01:20

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	12 NOV 2020
Collection time (<i>00:00-23:59</i>)	10:51 (24 HR)
Collection date and time (derived)	12 NOV 2020 10:51

US3802218

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 18:29:12

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2020 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 23:56:54
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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°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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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°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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3802218

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802218

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3802218

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 17:01:20

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3802218

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 17:01:20

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

AEID	USA-US098-2020-MRNA-1273-P30 1000001
Adverse event	PARAESOPHOGEAL HIATAL HERNIA WORSENING
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)	28 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)	5 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	28 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	5 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

340 of 1912

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

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	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

10/28/2020-ADMITTED PRIOR TO
SURGERY-PAST MEDICAL
HISTORY REPORT OF KNOWN
PARAESOPHAGEAL HERNIA
THAT HAS BEEN
EXPERIENCING WORSENING
SYMPTOMS. ADMITTED FOR A
LAPAROSCOPIC REPAIR OF
HERNIA. CXR:
CARDIOMEDIASTINAL
SILHOUETTE NOT ENLARGED,
INCLUDING HIATAL HERNIA,
PULMONARY VASCULAR
MARKINGS NOT ENLARGED,
LUNG VOLUMES NORMAL, NO
FOCAL CONSOLIDATION,
PLEURAL EFFUSION OR
SIGNIFICANT
PNEUMOTHORAX. NO ACUTE
OSSEOUS OR SOFT TISSUE
ABNORMALITIES 10/29/2020- VS
37.0, 97/62, 76, 16, 93%, 108KG,
34.9BMI 10/30/2020- REPAIR
HIATAL HERNIA LAPROSCOPIC,
ESOPHOGOSCOPY,
GASTROPEXY, ESTIMATED
BLOOD LOSS 10ML, FINDINGS:
GIANT PARAESOPHOGEAL
HERNIA WITH MAJORITY OF
STOMACH INTRATHORACIC
LAP GPEH REPAIR WITH
GASTROPEXY, HIATAL
CLOSURE WITH 2 POSTERIOR
STITCHES AND 3 STITCHES AT
3:00, LEFT PIGTAIL. VS 36.6,
115/60, 84, 16, 97% 10/31/2020- NO
ACUTE EVENTS OVERNIGHT,
ADEQUATE PAIN CONTROL.
CXR: SMALL AMOUNT OF LEFT
SUBPULMONIC EFFUSION LEFT
PIGTAIL CATHETER REMAINS
IN PLACE. 11/1/2020- VS 37.5,
84/52, 64, 17, 95%, CONTINUE
INPATIENT CARE

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

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

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 17:01:20

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

Yes ☒

No ☐

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

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

Name of Medication	TRIUMEQ
Prophylaxis	Yes ☐ No ☒
Indication	HIV
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	1 TABLET CONTAINS: 600 MG OF ABACAVIR, 50 MG OF DOLUTEGRAVIR, AND 300 MG OF LAMIVUDINE
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 ☐

v6.020 DTW (1102)

345 of 1912

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

	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)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

Name of Medication	LISINOPRIL
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
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 ☐

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

	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)		
Start date completely unknown		True
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 ☒

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

Name of Medication	GLIMEPIRIDE
Prophylaxis	Yes ☐ No ☒
Indication	DIABETES TYPE 2
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 ☐

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

	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)		
Start date completely unknown		True
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 ☒

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

Name of Medication	TAMSULOSIN
Prophylaxis	Yes ☐ No ☒
Indication	ENLARGED PROSTATE
Dose per administration	0.4
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 ☐

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

	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 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	☒

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

Name of Medication	ASPIRIN
Prophylaxis	Yes ☒ No ☐
Indication	HEART HEALTH
Dose per administration	81
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

	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)		
Start date completely unknown		True
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 ☒

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

Name of Medication	FENOFIBRATE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTRIGLYCERIDES
Dose per administration	48
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 ☐

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

	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)		
Start date completely unknown		True
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 ☒

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

Name of Medication	VENLAFAXINEER
Prophylaxis	Yes ☐ No ☒
Indication	ANXIETY
Dose per administration	150
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 ☐

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

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

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

Name of Medication	VENLAFAXINEER
Prophylaxis	Yes ☐ No ☒
Indication	ANXIETY
Dose per administration	75
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 ☐

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

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

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	HIGH CHOLESTEROL
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 ☐

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

	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)		
Start date completely unknown		True
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 ☒

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

Name of Medication	KENALOG OINTMENT
Prophylaxis	Yes ☐ No ☒
Indication	GENERALIZED RASH
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 ☐

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

	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 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

Name of Medication	LEVOCETIRIZINE
Prophylaxis	Yes ☐ No ☒
Indication	DUST ALLERGIES
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 ☐

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

Name of Medication	VITAMIN D3
Prophylaxis	Yes ☒ No ☐
Indication	SUPPLEMENT
Dose per administration	2000
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 ☐

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

Name of Medication	HEPARIN
Prophylaxis	Yes ☒ No ☐
Indication	CLOT PREVENTION
Dose per administration	5000
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNITS
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 ☐

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

	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)		29 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)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

Name of Medication	FLU VACCINE
Prophylaxis	Yes ☒
	No ☐
Indication	PREVENT INFLUENZA INFECTION
Dose per administration	UNK
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 ☐

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

	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)		6 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		6 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 17:01:20

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 17:01:20

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
30 OCT 2020	PARAESOPHAGEAL HERNIA REPAIR	Medical History	

US3802218

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 17:01:20

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

US3802218

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 17:01:20

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 ☐

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

SAEID	USA-US098-2020-MRNA-1273-P301000001
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	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 17:01:20

SAEID	USA-US098-2020-MRNA-1273-P301000001
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	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	03/NOV/2020 17:24
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

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 17:01:20

SAEID	USA-US098-2020-MRNA-1273-P301000001
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	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/NOV/2020 15:51
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

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 17:01:20

SAEID	USA-US098-2020-MRNA-1273-P301000001
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	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/NOV/2020 07:53
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

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 17:01:20

SAEID	USA-US098-2020-MRNA-1273-P301000001
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	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	16/NOV/2020 09:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3802218 (Prod: UPMC University Center)

US3802218

Form: Participant Creation

Generated On: 26 Nov 2020 17:01:20

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3802218'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Sep 2020 14:05:45

US3802218

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:03

US3802218

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Sep 2020 14:05:46

US3802218

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:03

US3802218

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	11 Sep 2020 14:08:03

US3802218

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 17:01:20

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1956'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Sep 2020 14:05:47

US3802218

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 17:01:20

[Age](#)

Audit	User	Time (GMT)
User entered '64'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:24

US3802218

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 17:01:20

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	11 Sep 2020 14:08:24

US3802218

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 17:01:20

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '64'	System	11 Sep 2020 14:08:42

US3802218

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 17:01:20

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:24

US3802218

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 17:01:20

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:24

US3802218

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 17:01:20

White

Audit	User	Time (GMT)
User entered '1'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:24

US3802218

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 17:01:20

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:24

US3802218

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 17:01:20

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:24

US3802218

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 17:01:20

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:24

US3802218

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 17:01:20

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:24

US3802218

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 17:01:20

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:24

US3802218

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 17:01:20

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:24

US3802218

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 17:01:20

Unknown

Audit	User	Time (GMT)
User entered '0'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:24

US3802218

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 17:01:20

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:24

US3802218

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:42

US3802218

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	11 Sep 2020 14:08:42

US3802218

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '2020'	System	11 Sep 2020 14:08:42

US3802218

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 17:01:20

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:42

US3802218

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:42

US3802218

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 17:01:20

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:42

US3802218

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 17:01:20

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:42

US3802218

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 17:01:20

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:42

US3802218

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 17:01:20

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Sep 2020 14:05:46

US3802218

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 17:01:20

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:08:48

US3802218

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:48

US3802218

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 17:01:20

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:09:11

US3802218

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 17:01:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Retroviral infections, PT: HIV infection, LLT: HIV infection - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 14:51:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 14:51:40
Data point term sent to Coder	System	11 Sep 2020 14:50:48
User entered 'HIV'	Lalicia Roman (b) (4)	11 Sep 2020 14:50:13
	(b) (4)	

US3802218

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:50:13

US3802218

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:50:13

US3802218

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 17:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:50:13

US3802218

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:50:13

US3802218

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 17:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:50:13

US3802218

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	11 Sep 2020 14:50:13

US3802218

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '2016'	System	11 Sep 2020 14:50:13

US3802218

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 14:50:13

US3802218

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 14:50:13

US3802218

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 17:01:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Dust allergy, LLT: Dust allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:18:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:18:37
Data point term sent to Coder	System	11 Sep 2020 15:17:33
User entered 'Dust Allergy'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:16:46

US3802218

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:16:46

US3802218

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:16:46

US3802218

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 17:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:16:46

US3802218

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:16:46

US3802218

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 17:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:16:46

US3802218

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 15:16:46

US3802218

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 15:16:46

US3802218

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 15:16:46

US3802218

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 15:16:46

US3802218

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 17:01:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 15:19:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 15:19:40
Data point term sent to Coder	System	11 Sep 2020 15:18:35
User entered 'Hiatal Hernia'	Dominic Kramer (b) (4)	11 Sep 2020 15:17:36

US3802218

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:17:36

US3802218

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:17:36

US3802218

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 17:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:17:36

US3802218

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:17:36

US3802218

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 17:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:17:36

US3802218

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 15:17:36

US3802218

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 15:17:36

US3802218

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 15:17:36

US3802218

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 15:17:36

US3802218

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 17:01:20

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location and type of Rash (Urticarial vs Non-urticarial). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 14:57:36
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Generalized rash - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 17:01:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 17:01:46
Data point term sent to Coder	System	13 Nov 2020 16:45:42
Coding entries removed.	Lalicia Roman (b) (4)	13 Nov 2020 16:45:39
User entered 'Generalized RASH' reason for change: Data Entry Error	Lalicia Roman (b) (4)	13 Nov 2020 16:45:39
Query 'Per DM CLR: Please specify the location and type of Rash (Urticarial vs Non-urticarial). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'participant did not disclose this information ' (Site from DM).	Emily Carney (b) (4)	29 Oct 2020 15:43:04
User opened query 'Per DM CLR: Please specify the location and type of Rash (Urticarial vs Non-urticarial). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:30:04
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 15:19:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 15:19:39
Data point term sent to Coder	System	11 Sep 2020 15:18:35

US3802218

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 17:01:20

[Condition](#)

Audit	User	Time (GMT)
User entered 'Rash'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:18:25

US3802218

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:18:25

US3802218

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:18:25

US3802218

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 17:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:18:25

US3802218

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:18:25

US3802218

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 17:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:18:25

US3802218

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	11 Sep 2020 15:18:25

US3802218

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '2015'	System	11 Sep 2020 15:18:25

US3802218

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 15:18:25

US3802218

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 15:18:25

US3802218

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 17:01:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 04:38:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 04:38:33
Data point term sent to Coder	System	19 Oct 2020 19:22:27
User entered 'enrionmental allergies'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:21:38

US3802218

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:21:38

US3802218

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:21:38

US3802218

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 17:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:21:38

US3802218

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:21:38

US3802218

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 17:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:21:38

US3802218

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:21:38

US3802218

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:21:38

US3802218

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:21:38

US3802218

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:21:38

US3802218

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 17:01:20

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 03:44:09
Query 'Per DM CLR: Please note that there is no Con Emily Carney Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Participant did not report taking a medication. This is what was reported but it is under the supervision of a physician. ' (Site from DM).	(b) (4)	29 Oct 2020 15:41:30
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 09:34:20
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)	19 Oct 2020 19:23:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 19:23:22
Data point term sent to Coder	System	19 Oct 2020 19:22:27
User entered 'hypertension'	Jennifer Nagg (b) (4)	19 Oct 2020 19:21:58

US3802218

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:21:58

US3802218

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:21:58

US3802218

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 17:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:21:58

US3802218

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:21:58

US3802218

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 17:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:21:58

US3802218

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:21:58

US3802218

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:21:58

US3802218

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:21:58

US3802218

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:21:58

US3802218

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 17:01:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:23:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:23:22
Data point term sent to Coder	System	19 Oct 2020 19:22:27
User entered 'diabetes type 2'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:22:19

US3802218

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:22:19

US3802218

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:22:19

US3802218

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 17:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:22:19

US3802218

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:22:19

US3802218

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 17:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:22:19

US3802218

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:22:19

US3802218

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:22:19

US3802218

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:22:19

US3802218

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:22:19

US3802218

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 17:01:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 19:24:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 19:24:26
Data point term sent to Coder	System	19 Oct 2020 19:23:29
User entered 'anxiety'	Jennifer Nagg (b) (4)	19 Oct 2020 19:22:37

US3802218

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:22:37

US3802218

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:22:37

US3802218

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 17:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:22:37

US3802218

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:22:37

US3802218

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 17:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:22:37

US3802218

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:22:37

US3802218

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:22:37

US3802218

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:22:37

US3802218

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:22:37

US3802218

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 17:01:20

[Condition](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 18:48:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:48:00
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 18:42:28
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 18:42:28
	(b) (4)	
Data point term sent to Coder	System	03 Nov 2020 18:41:42
Coding entries removed.	Emily Dougherty (b) (4)	03 Nov 2020 18:41:08
	(b) (4)	
User entered 'Enlarged Prostate' reason for change: Data Entry Error	Emily Dougherty (b) (4)	03 Nov 2020 18:41:08
	(b) (4)	
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatic disorder, LLT: Prostatic disorder - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 19:24:26
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 19:24:26
	(b) (4)	
Data point term sent to Coder	System	19 Oct 2020 19:23:30
User entered 'prostate problems'	Jennifer Nagg (b) (4)	19 Oct 2020 19:23:04
	(b) (4)	

US3802218

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:23:04

US3802218

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:23:04

US3802218

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 17:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:23:04

US3802218

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:23:04

US3802218

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 17:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:23:04

US3802218

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:23:04

US3802218

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:23:04

US3802218

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:23:04

US3802218

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:23:04

US3802218

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 17:01:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated triglycerides, PT: Hypertriglyceridaemia, LLT: Hypertriglyceridemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:27:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:27:35
Data point term sent to Coder	System	04 Nov 2020 20:44:37
User entered 'hypertriglycerides'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:43:42

US3802218

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:43:42

US3802218

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:43:42

US3802218

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 17:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:43:42

US3802218

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:43:42

US3802218

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 17:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:43:42

US3802218

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 20:43:42

US3802218

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 20:43:42

US3802218

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 20:43:42

US3802218

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 20:43:42

US3802218

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 17:01:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLG: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 05:17:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 05:17:36
Data point term sent to Coder	System	04 Nov 2020 20:47:43
User entered 'high choloesterol'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:47:10

US3802218

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:47:10

US3802218

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:47:10

US3802218

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 17:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:47:10

US3802218

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:47:10

US3802218

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 17:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:47:10

US3802218

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 20:47:10

US3802218

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 20:47:10

US3802218

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 20:47:10

US3802218

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 20:47:10

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '10:20'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 10:20'	System	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '172' cm	Dominic Kramer (b) (4)	11 Sep 2020 15:15:28
DataPoint set to visible.	(b) (4) System	11 Sep 2020 14:08:48

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '245' lb	Dominic Kramer (b) (4)	11 Sep 2020 15:15:28
DataPoint set to visible.	(b) (4) System	11 Sep 2020 14:08:48

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '37.64320'	System	11 Sep 2020 15:15:28
DataPoint set to visible.	System	11 Sep 2020 14:08:48

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	11 Sep 2020 15:15:28
DataPoint set to visible.	System	11 Sep 2020 14:08:48

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '96.8' F	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Infrared'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '18'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '107'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '69'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 17:01:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:09:23

US3802218

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 17:01:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:09:23

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

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)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

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)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

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)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

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)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

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)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '0'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

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'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '1'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

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'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '0'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 17:01:20

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:11:48

US3802218

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:11:48

US3802218

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:11:48

US3802218

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	11 Sep 2020 14:11:48

US3802218

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Sep 2020 14:16:06

US3802218

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '146137'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Sep 2020 14:16:06

US3802218

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Sep 2020 14:16:06

US3802218

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 17:01:20

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)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:18:41

US3802218

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:18:41

US3802218

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:18:41

US3802218

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 17:01:20

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User closed query 'Diabetes is not listed in Medical History Form. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 20:33:36
Query 'Diabetes is not listed in Medical History Form. Please verify and reconcile.' answered with 'added' (Site from CRA).	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:17:32
User opened query 'Diabetes is not listed in Medical History Form. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 03:13:37
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:18:41

US3802218

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 17:01:20

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:18:41

US3802218

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	19 Oct 2020 19:17:36
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 06:07:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:07:56

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 17:01:20

Height

Audit	User	Time (GMT)
User entered '172' cm	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 17:01:20

[Weight](#)

Audit	User	Time (GMT)
User entered '245.5' lb	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 17:01:20

Height

Audit	User	Time (GMT)
User entered '172' cm	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 17:01:20

Weight

Audit	User	Time (GMT)
User entered '245.5' lb	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '10:20'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 10:20'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '96.8' F	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Infrared'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '18'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '107'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '69'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 17:01:20

Height

Audit	User	Time (GMT)
User entered '172' cm	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 17:01:20

Weight

Audit	User	Time (GMT)
User entered '245.5' lb	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '11:21'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:21'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.1' F	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Infrared'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

Pulse (xxx)

Audit	User	Time (GMT)
User entered '65'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '18'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '99'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '62'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 17:01:20

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:25

US3802218

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 17:01:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:25

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:49:41

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:49:41

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:49:41

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 14:49:41

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:49:41

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '10:46'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:49:41

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 10:46'	System	11 Sep 2020 14:49:41

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:49:41

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	11 Sep 2020 14:49:41

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 14:49:41

US3802218

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 17:01:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:18:56

US3802218

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 17:01:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:18:56

US3802218

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 17:01:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:34'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:18:56

US3802218

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 10:34'	System	11 Sep 2020 15:18:56

US3802218

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 17:01:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:19:42

US3802218

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 17:01:20

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:19:42

US3802218

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 17:01:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:19:42

US3802218

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 17:01:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:29'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:19:42

US3802218

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 10:29'	System	11 Sep 2020 15:19:42

US3802218

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 17:01:20

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dominic Kramer (b) (4)	11 Sep 2020 15:19:42

US3802218

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 17:01:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:19:42

US3802218

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 17:01:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:19:42

US3802218

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 15:19:42

US3802218

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:51:12

US3802218

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:51:12

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:26:13', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'af07f36f-07bf-4aa1-9b45-abe59dbc606c'	System	11 Sep 2020 15:26:39
User entered 'Yes (Y)'	System	11 Sep 2020 15:26:39

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:26:22', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'af07f36f-07bf-4aa1-9b45-abe59dbc606c'	System	11 Sep 2020 15:26:39
User entered '97.1'	System	11 Sep 2020 15:26:39

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:26:27', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'af07f36f-07bf-4aa1-9b45-abe59dbc606c'	System	11 Sep 2020 15:26:39
User entered 'No (N)'	System	11 Sep 2020 15:26:39

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:26:35', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'af07f36f-07bf-4aa1-9b45-abe59dbc606c'	System	11 Sep 2020 15:26:39
User entered '11 Sep 2020 11:26'	System	11 Sep 2020 15:26:39

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:06'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 13:36'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:54:49', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'b596b9c5-f18f-4fbe-b2ab-09310a17e2f0'	System	12 Sep 2020 02:55:19
User entered 'Yes (Y)'	System	12 Sep 2020 02:55:19

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:54:57', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'b596b9c5-f18f-4fbe-b2ab-09310a17e2f0'	System	12 Sep 2020 02:55:19
User entered '97.6'	System	12 Sep 2020 02:55:19

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:55:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'b596b9c5-f18f-4fbe-b2ab-09310a17e2f0'	System	12 Sep 2020 02:55:19
User entered 'No (N)'	System	12 Sep 2020 02:55:19

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:55:12', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'b596b9c5-f18f-4fbe-b2ab-09310a17e2f0'	System	12 Sep 2020 02:55:19
User entered '11 Sep 2020 22:55'	System	12 Sep 2020 02:55:19

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 14:31'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 2'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 17:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T20:39:32', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '638d6a32-bb93-4f16-a358-6b58f4cc99da'	System	13 Sep 2020 00:39:56
User entered 'Yes (Y)'	System	13 Sep 2020 00:39:56

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 17:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T20:39:41', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '638d6a32-bb93-4f16-a358-6b58f4cc99da'	System	13 Sep 2020 00:39:56
User entered '98.0'	System	13 Sep 2020 00:39:56

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T20:39:44', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '638d6a32-bb93-4f16-a358-6b58f4cc99da'	System	13 Sep 2020 00:39:56
User entered 'No (N)'	System	13 Sep 2020 00:39:56

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T20:39:50', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '638d6a32-bb93-4f16-a358-6b58f4cc99da'	System	13 Sep 2020 00:39:56
User entered '12 Sep 2020 20:39'	System	13 Sep 2020 00:39:56

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 3'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 17:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T21:57:31', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'a7ca690d-cfc1-44ea-ba2c-c10c41e53a64'	System	14 Sep 2020 01:57:59
User entered 'Yes (Y)'	System	14 Sep 2020 01:57:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 17:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T21:57:42', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'a7ca690d-cfc1-44ea-ba2c-c10c41e53a64'	System	14 Sep 2020 01:57:59
User entered '98.6'	System	14 Sep 2020 01:57:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T21:57:45', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'a7ca690d-cfc1-44ea-ba2c-c10c41e53a64'	System	14 Sep 2020 01:57:59
User entered 'No (N)'	System	14 Sep 2020 01:57:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T21:57:50', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'a7ca690d-cfc1-44ea-ba2c-c10c41e53a64'	System	14 Sep 2020 01:57:59
User entered '13 Sep 2020 21:57'	System	14 Sep 2020 01:57:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 4'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 17:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'b23b66fe-cd41-4aae-a8cd-3f5f616db4d4'	System	14 Sep 2020 18:36:27
User entered 'Yes (Y)'	System	14 Sep 2020 18:36:27

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 17:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:13', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'b23b66fe-cd41-4aae-a8cd-3f5f616db4d4'	System	14 Sep 2020 18:36:27
User entered '98.1'	System	14 Sep 2020 18:36:27

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:16', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'b23b66fe-cd41-4aae-a8cd-3f5f616db4d4'	System	14 Sep 2020 18:36:27
User entered 'No (N)'	System	14 Sep 2020 18:36:27

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:21', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'b23b66fe-cd41-4aae-a8cd-3f5f616db4d4'	System	14 Sep 2020 18:36:27
User entered '14 Sep 2020 14:36'	System	14 Sep 2020 18:36:27

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 5'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 17:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1d26d061-2c19-4921-9f27-71b2a29b9ae7'	System	15 Sep 2020 18:01:27
User entered 'Yes (Y)'	System	15 Sep 2020 18:01:27

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 17:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1d26d061-2c19-4921-9f27-71b2a29b9ae7'	System	15 Sep 2020 18:01:27
User entered '97.9'	System	15 Sep 2020 18:01:27

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:11', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1d26d061-2c19-4921-9f27-71b2a29b9ae7'	System	15 Sep 2020 18:01:27
User entered 'No (N)'	System	15 Sep 2020 18:01:27

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:19', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1d26d061-2c19-4921-9f27-71b2a29b9ae7'	System	15 Sep 2020 18:01:27
User entered '15 Sep 2020 14:01'	System	15 Sep 2020 18:01:27

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 6'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 17:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T00:09:03', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4298b35a-a76f-4c5f-9002-58d30c298712'	System	17 Sep 2020 04:09:24
User entered 'Yes (Y)'	System	17 Sep 2020 04:09:24

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 17:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T00:09:11', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4298b35a-a76f-4c5f-9002-58d30c298712'	System	17 Sep 2020 04:09:24
User entered '98.1'	System	17 Sep 2020 04:09:24

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T00:09:14', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4298b35a-a76f-4c5f-9002-58d30c298712'	System	17 Sep 2020 04:09:24
User entered 'No (N)'	System	17 Sep 2020 04:09:24

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T00:09:20', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4298b35a-a76f-4c5f-9002-58d30c298712'	System	17 Sep 2020 04:09:24
User entered '17 Sep 2020 00:09'	System	17 Sep 2020 04:09:24

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 7'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 17:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:58:39', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '3741d864-ad5f-4e46-9c3d-93ffa0edd6cc'	System	17 Sep 2020 22:59:23
User entered 'Yes (Y)'	System	17 Sep 2020 22:59:23

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 17:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:58:48', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '3741d864-ad5f-4e46-9c3d-93ffa0edd6cc'	System	17 Sep 2020 22:59:23
User entered '98.1'	System	17 Sep 2020 22:59:23

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:58:52', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '3741d864-ad5f-4e46-9c3d-93ffa0edd6cc'	System	17 Sep 2020 22:59:23
User entered 'No (N)'	System	17 Sep 2020 22:59:23

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:58:58', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '3741d864-ad5f-4e46-9c3d-93ffa0edd6cc'	System	17 Sep 2020 22:59:23
User entered '17 Sep 2020 18:58'	System	17 Sep 2020 22:59:23

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-11T11:26:47', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '09d506fc-02ba-45f1-b4a2-83a428c52114'	System	11 Sep 2020 15:27:08
User entered 'None (1)'	System	11 Sep 2020 15:27:08

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:26:51', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '09d506fc-02ba-45f1-b4a2-83a428c52114'	System	11 Sep 2020 15:27:08
User entered 'No (N)'	System	11 Sep 2020 15:27:08

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:26:55', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '09d506fc-02ba-45f1-b4a2-83a428c52114'	System	11 Sep 2020 15:27:08
User entered 'No (N)'	System	11 Sep 2020 15:27:08

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-11T11:26:59', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '09d506fc-02ba-45f1-b4a2-83a428c52114'	System	11 Sep 2020 15:27:08
User entered 'None (1)'	System	11 Sep 2020 15:27:08

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:27:04', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '09d506fc-02ba-45f1-b4a2-83a428c52114'	System	11 Sep 2020 15:27:08
User entered '11 Sep 2020 11:27'	System	11 Sep 2020 15:27:08

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:06'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 13:36'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-11T22:55:34', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'ae892d38-ba7a-4d4b-b14c-f222c5590437'	System	12 Sep 2020 02:56:16
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 02:56:16

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:55:40', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'ae892d38-ba7a-4d4b-b14c-f222c5590437'	System	12 Sep 2020 02:56:16
User entered 'No (N)'	System	12 Sep 2020 02:56:16

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:55:50', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'ae892d38-ba7a-4d4b-b14c-f222c5590437'	System	12 Sep 2020 02:56:16
User entered 'No (N)'	System	12 Sep 2020 02:56:16

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-11T22:55:57', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'ae892d38-ba7a-4d4b-b14c-f222c5590437'	System	12 Sep 2020 02:56:16
User entered 'None (1)'	System	12 Sep 2020 02:56:16

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:56:09', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'ae892d38-ba7a-4d4b-b14c-f222c5590437'	System	12 Sep 2020 02:56:16
User entered '11 Sep 2020 22:56'	System	12 Sep 2020 02:56:16

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 14:31'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 2'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-12T15:52:20', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fcdd2e9e-738c-4c30-9f19-3b787057e7b2'	System	12 Sep 2020 19:52:41
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 19:52:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 17:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:52:24', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fcdd2e9e-738c-4c30-9f19-3b787057e7b2'	System	12 Sep 2020 19:52:41
User entered 'No (N)'	System	12 Sep 2020 19:52:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:52:27', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fcdd2e9e-738c-4c30-9f19-3b787057e7b2'	System	12 Sep 2020 19:52:41
User entered 'No (N)'	System	12 Sep 2020 19:52:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-12T15:52:30', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fcdd2e9e-738c-4c30-9f19-3b787057e7b2'	System	12 Sep 2020 19:52:41
User entered 'None (1)'	System	12 Sep 2020 19:52:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:52:36', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fcdd2e9e-738c-4c30-9f19-3b787057e7b2'	System	12 Sep 2020 19:52:41
User entered '12 Sep 2020 15:52'	System	12 Sep 2020 19:52:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 3'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-13T17:09:46', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'af406d91-0618-4db8-b683-bbeab74ff340'	System	13 Sep 2020 21:10:04
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 21:10:04

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 17:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:09:49', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'af406d91-0618-4db8-b683-bbeab74ff340'	System	13 Sep 2020 21:10:04
User entered 'No (N)'	System	13 Sep 2020 21:10:04

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:09:52', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'af406d91-0618-4db8-b683-bbeab74ff340'	System	13 Sep 2020 21:10:04
User entered 'No (N)'	System	13 Sep 2020 21:10:04

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-13T17:09:55', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'af406d91-0618-4db8-b683-bbeab74ff340'	System	13 Sep 2020 21:10:04
User entered 'None (1)'	System	13 Sep 2020 21:10:04

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:10:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'af406d91-0618-4db8-b683-bbeab74ff340'	System	13 Sep 2020 21:10:04
User entered '13 Sep 2020 17:10'	System	13 Sep 2020 21:10:04

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 4'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 17:01:20

[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 (390c60986467e739)', Time: '2020-09-14T14:36:29', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '331bde5c-e0a2-4fd3-9333-0c971adb62ab'	System	14 Sep 2020 18:36:51
User entered 'None (1)'	System	14 Sep 2020 18:36:51

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 17:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:32', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '331bde5c-e0a2-4fd3-9333-0c971adb62ab'	System	14 Sep 2020 18:36:51
User entered 'No (N)'	System	14 Sep 2020 18:36:51

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:34', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '331bde5c-e0a2-4fd3-9333-0c971adb62ab'	System	14 Sep 2020 18:36:51
User entered 'No (N)'	System	14 Sep 2020 18:36:51

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-14T14:36:39', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '331bde5c-e0a2-4fd3-9333-0c971adb62ab'	System	14 Sep 2020 18:36:51
User entered 'None (1)'	System	14 Sep 2020 18:36:51

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:44', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '331bde5c-e0a2-4fd3-9333-0c971adb62ab'	System	14 Sep 2020 18:36:51
User entered '14 Sep 2020 14:36'	System	14 Sep 2020 18:36:51

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 5'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-15T14:01:25', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fdd98001-86d8-49d5-b45c-d65dea1743aa'	System	15 Sep 2020 18:01:42
User entered 'None (1)'	System	15 Sep 2020 18:01:42

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 17:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:27', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fdd98001-86d8-49d5-b45c-d65dea1743aa'	System	15 Sep 2020 18:01:42
User entered 'No (N)'	System	15 Sep 2020 18:01:42

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:30', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fdd98001-86d8-49d5-b45c-d65dea1743aa'	System	15 Sep 2020 18:01:42
User entered 'No (N)'	System	15 Sep 2020 18:01:42

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-15T14:01:33', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fdd98001-86d8-49d5-b45c-d65dea1743aa'	System	15 Sep 2020 18:01:42
User entered 'None (1)'	System	15 Sep 2020 18:01:42

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:39', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fdd98001-86d8-49d5-b45c-d65dea1743aa'	System	15 Sep 2020 18:01:42
User entered '15 Sep 2020 14:01'	System	15 Sep 2020 18:01:42

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 6'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-16T18:24:40', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8bdc7671-44a9-48c9-a9b3-10db4ce3caf1'	System	16 Sep 2020 22:24:58
User entered 'None (1)'	System	16 Sep 2020 22:24:58

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 17:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:24:43', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8bdc7671-44a9-48c9-a9b3-10db4ce3caf1'	System	16 Sep 2020 22:24:58
User entered 'No (N)'	System	16 Sep 2020 22:24:58

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:24:46', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8bdc7671-44a9-48c9-a9b3-10db4ce3caf1'	System	16 Sep 2020 22:24:58
User entered 'No (N)'	System	16 Sep 2020 22:24:58

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-16T18:24:48', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8bdc7671-44a9-48c9-a9b3-10db4ce3caf1'	System	16 Sep 2020 22:24:58
User entered 'None (1)'	System	16 Sep 2020 22:24:58

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:24:55', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8bdc7671-44a9-48c9-a9b3-10db4ce3caf1'	System	16 Sep 2020 22:24:58
User entered '16 Sep 2020 18:24'	System	16 Sep 2020 22:24:58

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 7'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-17T18:59:05', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '83c384c9-6a26-4466-bbb8-47ab4efb317b'	System	17 Sep 2020 22:59:29
User entered 'None (1)'	System	17 Sep 2020 22:59:29

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 17:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '83c384c9-6a26-4466-bbb8-47ab4efb317b'	System	17 Sep 2020 22:59:29
User entered 'No (N)'	System	17 Sep 2020 22:59:29

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:11', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '83c384c9-6a26-4466-bbb8-47ab4efb317b'	System	17 Sep 2020 22:59:29
User entered 'No (N)'	System	17 Sep 2020 22:59:29

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-17T18:59:14', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '83c384c9-6a26-4466-bbb8-47ab4efb317b'	System	17 Sep 2020 22:59:29
User entered 'None (1)'	System	17 Sep 2020 22:59:29

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:21', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '83c384c9-6a26-4466-bbb8-47ab4efb317b'	System	17 Sep 2020 22:59:29
User entered '17 Sep 2020 18:59'	System	17 Sep 2020 22:59:29

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:27:11', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'bc7e8cc1-7d33-4541-bb88-98bb6bae3247'	System	11 Sep 2020 15:27:48
User entered 'None (0)'	System	11 Sep 2020 15:27:48

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:27:15', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'bc7e8cc1-7d33-4541-bb88-98bb6bae3247'	System	11 Sep 2020 15:27:48
User entered 'None (0)'	System	11 Sep 2020 15:27:48

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:27:17', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'bc7e8cc1-7d33-4541-bb88-98bb6bae3247'	System	11 Sep 2020 15:27:48
User entered 'None (0)'	System	11 Sep 2020 15:27:48

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:27:20', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'bc7e8cc1-7d33-4541-bb88-98bb6bae3247'	System	11 Sep 2020 15:27:48
User entered 'None (0)'	System	11 Sep 2020 15:27:48

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:27:22', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'bc7e8cc1-7d33-4541-bb88-98bb6bae3247'	System	11 Sep 2020 15:27:48
User entered 'None (0)'	System	11 Sep 2020 15:27:48

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:27:24', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'bc7e8cc1-7d33-4541-bb88-98bb6bae3247'	System	11 Sep 2020 15:27:48
User entered 'None (0)'	System	11 Sep 2020 15:27:48

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-11T11:27:28', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'bc7e8cc1-7d33-4541-bb88-98bb6bae3247'	System	11 Sep 2020 15:27:48
User entered 'No (N)'	System	11 Sep 2020 15:27:48

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:27:32', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'bc7e8cc1-7d33-4541-bb88-98bb6bae3247'	System	11 Sep 2020 15:27:48
User entered '11 Sep 2020 11:27'	System	11 Sep 2020 15:27:48

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:06'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 13:36'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:56:34', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'c8cd848b-4eb9-4933-8be2-1be1ce330e55'	System	12 Sep 2020 02:57:12
User entered 'None (0)'	System	12 Sep 2020 02:57:12

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:56:39', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'c8cd848b-4eb9-4933-8be2-1be1ce330e55'	System	12 Sep 2020 02:57:12
User entered 'None (0)'	System	12 Sep 2020 02:57:12

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:56:42', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'c8cd848b-4eb9-4933-8be2-1be1ce330e55'	System	12 Sep 2020 02:57:12
User entered 'None (0)'	System	12 Sep 2020 02:57:12

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:56:46', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'c8cd848b-4eb9-4933-8be2-1be1ce330e55'	System	12 Sep 2020 02:57:12
User entered 'None (0)'	System	12 Sep 2020 02:57:12

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:56:49', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'c8cd848b-4eb9-4933-8be2-1be1ce330e55'	System	12 Sep 2020 02:57:12
User entered 'None (0)'	System	12 Sep 2020 02:57:12

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:56:51', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'c8cd848b-4eb9-4933-8be2-1be1ce330e55'	System	12 Sep 2020 02:57:12
User entered 'None (0)'	System	12 Sep 2020 02:57:12

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-11T22:56:56', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'c8cd848b-4eb9-4933-8be2-1be1ce330e55'	System	12 Sep 2020 02:57:12
User entered 'No (N)'	System	12 Sep 2020 02:57:12

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:57:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'c8cd848b-4eb9-4933-8be2-1be1ce330e55'	System	12 Sep 2020 02:57:12
User entered '11 Sep 2020 22:57'	System	12 Sep 2020 02:57:12

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 14:31'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 2'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:51:20', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e8e7f807-1c27-4e9a-b42c-66619e62cb58'	System	12 Sep 2020 19:52:14
User entered 'None (0)'	System	12 Sep 2020 19:52:14

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:51:28', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e8e7f807-1c27-4e9a-b42c-66619e62cb58'	System	12 Sep 2020 19:52:14
User entered 'None (0)'	System	12 Sep 2020 19:52:14

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:51:59', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e8e7f807-1c27-4e9a-b42c-66619e62cb58'	System	12 Sep 2020 19:52:14
User entered 'None (0)'	System	12 Sep 2020 19:52:14

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:51:56', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e8e7f807-1c27-4e9a-b42c-66619e62cb58'	System	12 Sep 2020 19:52:14
User entered 'None (0)'	System	12 Sep 2020 19:52:14

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:51:55', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e8e7f807-1c27-4e9a-b42c-66619e62cb58'	System	12 Sep 2020 19:52:14
User entered 'None (0)'	System	12 Sep 2020 19:52:14

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:51:53', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e8e7f807-1c27-4e9a-b42c-66619e62cb58'	System	12 Sep 2020 19:52:14
User entered 'None (0)'	System	12 Sep 2020 19:52:14

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-12T15:51:53', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e8e7f807-1c27-4e9a-b42c-66619e62cb58'	System	12 Sep 2020 19:52:14
User entered 'No (N)'	System	12 Sep 2020 19:52:14

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:52:12', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e8e7f807-1c27-4e9a-b42c-66619e62cb58'	System	12 Sep 2020 19:52:14
User entered '12 Sep 2020 15:52'	System	12 Sep 2020 19:52:14

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 3'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:08:55', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '63add730-53a7-4580-b023-e25c890a3d49'	System	13 Sep 2020 21:09:43
User entered 'None (0)'	System	13 Sep 2020 21:09:43

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:09:36', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '63add730-53a7-4580-b023-e25c890a3d49'	System	13 Sep 2020 21:09:43
User entered 'None (0)'	System	13 Sep 2020 21:09:43

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:08:36', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '63add730-53a7-4580-b023-e25c890a3d49'	System	13 Sep 2020 21:09:43
User entered 'None (0)'	System	13 Sep 2020 21:09:43

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:09:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '63add730-53a7-4580-b023-e25c890a3d49'	System	13 Sep 2020 21:09:43
User entered 'None (0)'	System	13 Sep 2020 21:09:43

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:09:07', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '63add730-53a7-4580-b023-e25c890a3d49'	System	13 Sep 2020 21:09:43
User entered 'None (0)'	System	13 Sep 2020 21:09:43

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:09:10', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '63add730-53a7-4580-b023-e25c890a3d49'	System	13 Sep 2020 21:09:43
User entered 'None (0)'	System	13 Sep 2020 21:09:43

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-13T17:09:13', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '63add730-53a7-4580-b023-e25c890a3d49'	System	13 Sep 2020 21:09:43
User entered 'No (N)'	System	13 Sep 2020 21:09:43

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:09:40', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '63add730-53a7-4580-b023-e25c890a3d49'	System	13 Sep 2020 21:09:43
User entered '13 Sep 2020 17:09'	System	13 Sep 2020 21:09:43

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 4'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:50', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '538d5012-4413-4bc9-9790-102266c7c9bb'	System	14 Sep 2020 18:37:22
User entered 'None (0)'	System	14 Sep 2020 18:37:22

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:56', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '538d5012-4413-4bc9-9790-102266c7c9bb'	System	14 Sep 2020 18:37:22
User entered 'None (0)'	System	14 Sep 2020 18:37:22

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:37:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '538d5012-4413-4bc9-9790-102266c7c9bb'	System	14 Sep 2020 18:37:22
User entered 'None (0)'	System	14 Sep 2020 18:37:22

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:37:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '538d5012-4413-4bc9-9790-102266c7c9bb'	System	14 Sep 2020 18:37:22
User entered 'None (0)'	System	14 Sep 2020 18:37:22

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:37:04', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '538d5012-4413-4bc9-9790-102266c7c9bb'	System	14 Sep 2020 18:37:22
User entered 'None (0)'	System	14 Sep 2020 18:37:22

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:37:06', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '538d5012-4413-4bc9-9790-102266c7c9bb'	System	14 Sep 2020 18:37:22
User entered 'None (0)'	System	14 Sep 2020 18:37:22

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-14T14:37:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '538d5012-4413-4bc9-9790-102266c7c9bb'	System	14 Sep 2020 18:37:22
User entered 'No (N)'	System	14 Sep 2020 18:37:22

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:37:15', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '538d5012-4413-4bc9-9790-102266c7c9bb'	System	14 Sep 2020 18:37:22
User entered '14 Sep 2020 14:37'	System	14 Sep 2020 18:37:22

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 5'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:43', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4e226ade-c1e7-4783-a53a-77b40fc94958'	System	15 Sep 2020 18:02:10
User entered 'None (0)'	System	15 Sep 2020 18:02:10

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:45', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4e226ade-c1e7-4783-a53a-77b40fc94958'	System	15 Sep 2020 18:02:10
User entered 'None (0)'	System	15 Sep 2020 18:02:10

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:47', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4e226ade-c1e7-4783-a53a-77b40fc94958'	System	15 Sep 2020 18:02:10
User entered 'None (0)'	System	15 Sep 2020 18:02:10

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:50', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4e226ade-c1e7-4783-a53a-77b40fc94958'	System	15 Sep 2020 18:02:10
User entered 'None (0)'	System	15 Sep 2020 18:02:10

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:52', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4e226ade-c1e7-4783-a53a-77b40fc94958'	System	15 Sep 2020 18:02:10
User entered 'None (0)'	System	15 Sep 2020 18:02:10

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:56', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4e226ade-c1e7-4783-a53a-77b40fc94958'	System	15 Sep 2020 18:02:10
User entered 'None (0)'	System	15 Sep 2020 18:02:10

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-15T14:01:59', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4e226ade-c1e7-4783-a53a-77b40fc94958'	System	15 Sep 2020 18:02:10
User entered 'No (N)'	System	15 Sep 2020 18:02:10

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:02:05', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4e226ade-c1e7-4783-a53a-77b40fc94958'	System	15 Sep 2020 18:02:10
User entered '15 Sep 2020 14:02'	System	15 Sep 2020 18:02:10

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 6'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:24:59', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '61bcf273-953c-4ebd-9c44-ea128d1bae23'	System	16 Sep 2020 22:25:21
User entered 'None (0)'	System	16 Sep 2020 22:25:21

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:25:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '61bcf273-953c-4ebd-9c44-ea128d1bae23'	System	16 Sep 2020 22:25:21
User entered 'None (0)'	System	16 Sep 2020 22:25:21

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:25:04', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '61bcf273-953c-4ebd-9c44-ea128d1bae23'	System	16 Sep 2020 22:25:21
User entered 'None (0)'	System	16 Sep 2020 22:25:21

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:25:06', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '61bcf273-953c-4ebd-9c44-ea128d1bae23'	System	16 Sep 2020 22:25:21
User entered 'None (0)'	System	16 Sep 2020 22:25:21

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:25:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '61bcf273-953c-4ebd-9c44-ea128d1bae23'	System	16 Sep 2020 22:25:21
User entered 'None (0)'	System	16 Sep 2020 22:25:21

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:25:11', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '61bcf273-953c-4ebd-9c44-ea128d1bae23'	System	16 Sep 2020 22:25:21
User entered 'None (0)'	System	16 Sep 2020 22:25:21

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-16T18:25:13', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '61bcf273-953c-4ebd-9c44-ea128d1bae23'	System	16 Sep 2020 22:25:21
User entered 'No (N)'	System	16 Sep 2020 22:25:21

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:25:17', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '61bcf273-953c-4ebd-9c44-ea128d1bae23'	System	16 Sep 2020 22:25:21
User entered '16 Sep 2020 18:25'	System	16 Sep 2020 22:25:21

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 7'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:31', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afa99a39-3ea8-49de-b2e1-6fa81f860188'	System	17 Sep 2020 23:00:03
User entered 'No interference with activity (1)'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:34', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afa99a39-3ea8-49de-b2e1-6fa81f860188'	System	17 Sep 2020 23:00:03
User entered 'None (0)'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:40', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afa99a39-3ea8-49de-b2e1-6fa81f860188'	System	17 Sep 2020 23:00:03
User entered 'None (0)'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:42', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afa99a39-3ea8-49de-b2e1-6fa81f860188'	System	17 Sep 2020 23:00:03
User entered 'None (0)'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:45', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afa99a39-3ea8-49de-b2e1-6fa81f860188'	System	17 Sep 2020 23:00:03
User entered 'None (0)'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:47', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afa99a39-3ea8-49de-b2e1-6fa81f860188'	System	17 Sep 2020 23:00:03
User entered 'None (0)'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-17T18:59:50', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afa99a39-3ea8-49de-b2e1-6fa81f860188'	System	17 Sep 2020 23:00:03
User entered 'No (N)'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:58', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afa99a39-3ea8-49de-b2e1-6fa81f860188'	System	17 Sep 2020 23:00:03
User entered '17 Sep 2020 18:59'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 23:00:03
User entered 'Day 8'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-19T03:15:56', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8d5527aa-3c5b-4e6b-90fc-cc6e1ca79fc8'	System	19 Sep 2020 07:16:07
User entered 'None (0)'	System	19 Sep 2020 07:16:07

US3802218

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-19T03:16:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8d5527aa-3c5b-4e6b-90fc-cc6e1ca79fc8'	System	19 Sep 2020 07:16:07
User entered '19 Sep 2020 03:16'	System	19 Sep 2020 07:16:07

US3802218

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 23:00:03
User entered 'Day 8'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-09-19T03:16:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '13baba6f-6d6d-413e-8684-c24e84b88d3a'	System	19 Sep 2020 07:16:13
User entered 'No (N)'	System	19 Sep 2020 07:16:13

US3802218

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 17:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-19T03:16:11', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '13baba6f-6d6d-413e-8684-c24e84b88d3a'	System	19 Sep 2020 07:16:13
User entered '19 Sep 2020 03:16'	System	19 Sep 2020 07:16:13

US3802218

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 23:00:03

US3802218

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	21 Sep 2020 19:19:59

US3802218

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Dominic Kramer (b) (4) (b) (4)	21 Sep 2020 19:19:59

US3802218

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	Dominic Kramer (b) (4) (b) (4)	21 Sep 2020 19:19:59

US3802218

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Patient contact attempted on three separate occasions. Patient was unable to be reached.'	Dominic Kramer (b) (4)	21 Sep 2020 19:19:59

US3802218

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	21 Sep 2020 19:20:04

US3802218

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 19:20:04

US3802218

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	25 Sep 2020 19:09:46

US3802218

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Dominic Kramer (b) (4) (b) (4)	25 Sep 2020 19:09:46

US3802218

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Dominic Kramer (b) (4) (b) (4)	25 Sep 2020 19:09:46

US3802218

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Dominic Kramer (b) (4) (b) (4)	25 Sep 2020 19:09:46

US3802218

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	25 Sep 2020 19:09:34

US3802218

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 19:09:34

US3802218

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	05 Oct 2020 12:49:04

US3802218

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '5 Oct 2020' reason for change: Data Entry Error	Emily Dougherty (b) (4)	05 Oct 2020 18:27:04
User entered '4 Oct 2020'	Jennifer Nagg (b) (4)	05 Oct 2020 12:49:04

US3802218

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Emily Dougherty (b) (4) (b) (4)	05 Oct 2020 18:27:04
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jennifer Nagg (b) (4) (b) (4)	05 Oct 2020 12:49:04

US3802218

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Three attempts unsuccessful'	Jennifer Nagg (b) (4) (b) (4)	05 Oct 2020 12:49:04

US3802218

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	05 Oct 2020 12:49:10

US3802218

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 12:49:10

US3802218

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:00:26

US3802218

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:00:26

US3802218

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:00:26

US3802218

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	13 Oct 2020 15:00:26

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '10:43'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 10:43'	System	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM-Requery: Site response noted, however, temperature is abnormal. Kindly confirm in the response if this is NCS or CS' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 14:22:11
Query 'Per CDM-Requery: Site response noted, however, temperature is abnormal. Kindly confirm in the response if this is NCS or CS' answered with 'ncs' (Site from DM).	Melissa Andrasko (b) (4)	14 Oct 2020 20:09:00
User opened query 'Per CDM-Requery: Site response noted, however, temperature is abnormal. Kindly confirm in the response if this is NCS or CS' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 06:56:04
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 06:51:53
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Actual value ' (Site from System).	Dominic Kramer (b) (4)	13 Oct 2020 15:52:57
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	13 Oct 2020 15:51:11
User entered '95.2' F	Dominic Kramer (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Infrared'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

Pulse (xxx)

Audit	User	Time (GMT)
User entered '108'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '18'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '141'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '84'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 17:01:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '11:44'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:44'	System	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '96.8' F	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Infrared'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

Pulse (xxx)

Audit	User	Time (GMT)
User entered '84'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '18'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '107'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 17:01:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 17:01:20

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:00:31

US3802218

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 17:01:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:00:31

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	13 Oct 2020 15:16:41

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Lalicia Roman (b) (4) (b) (4)	13 Oct 2020 15:16:41

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	Lalicia Roman (b) (4) (b) (4)	13 Oct 2020 15:16:41

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 15:16:41

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Lalicia Roman (b) (4) (b) (4)	13 Oct 2020 15:16:41

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '11:12'	Lalicia Roman (b) (4) (b) (4)	13 Oct 2020 15:16:41

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:12'	System	13 Oct 2020 15:16:41

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Lalicia Roman (b) (4) (b) (4)	13 Oct 2020 15:16:41

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	13 Oct 2020 15:16:41

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 15:16:41

US3802218

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 17:01:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:00:47

US3802218

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 17:01:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:00:47

US3802218

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 17:01:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:52'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:00:47

US3802218

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 10:52'	System	13 Oct 2020 15:00:47

US3802218

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 17:01:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:01:10

US3802218

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 17:01:20

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:01:10

US3802218

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 17:01:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:01:10

US3802218

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 17:01:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:48'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:01:10

US3802218

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 10:48'	System	13 Oct 2020 15:01:10

US3802218

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 17:01:20

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:01:10

US3802218

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 17:01:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:01:10

US3802218

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 17:01:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:01:10

US3802218

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:01:10

US3802218

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:01:16

US3802218

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 15:01:16

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:07', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '219641e5-5506-4db1-8247-abd5aeb50217'	System	13 Oct 2020 15:46:31
User entered 'Yes (Y)'	System	13 Oct 2020 15:46:31

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:14', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '219641e5-5506-4db1-8247-abd5aeb50217'	System	13 Oct 2020 15:46:31
User entered '96.8'	System	13 Oct 2020 15:46:31

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:18', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '219641e5-5506-4db1-8247-abd5aeb50217'	System	13 Oct 2020 15:46:31
User entered 'No (N)'	System	13 Oct 2020 15:46:31

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:23', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '219641e5-5506-4db1-8247-abd5aeb50217'	System	13 Oct 2020 15:46:31
User entered '13 Oct 2020 11:46'	System	13 Oct 2020 15:46:31

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:32'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:02'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:50:07', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f24cf4ac-3318-451b-ac24-a7d82b208355'	System	14 Oct 2020 01:50:40
User entered 'Yes (Y)'	System	14 Oct 2020 01:50:40

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:50:25', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f24cf4ac-3318-451b-ac24-a7d82b208355'	System	14 Oct 2020 01:50:40
User entered '97.1'	System	14 Oct 2020 01:50:40

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:50:28', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f24cf4ac-3318-451b-ac24-a7d82b208355'	System	14 Oct 2020 01:50:40
User entered 'No (N)'	System	14 Oct 2020 01:50:40

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:50:34', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f24cf4ac-3318-451b-ac24-a7d82b208355'	System	14 Oct 2020 01:50:40
User entered '13 Oct 2020 21:50'	System	14 Oct 2020 01:50:40

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:57'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 2'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 17:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:18:56', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '44622ff5-6090-4329-8c39-42034595c755'	System	15 Oct 2020 05:19:26
User entered 'Yes (Y)'	System	15 Oct 2020 05:19:26

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 17:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:19:05', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '44622ff5-6090-4329-8c39-42034595c755'	System	15 Oct 2020 05:19:26
User entered '98.2'	System	15 Oct 2020 05:19:26

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:19:09', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '44622ff5-6090-4329-8c39-42034595c755'	System	15 Oct 2020 05:19:26
User entered 'No (N)'	System	15 Oct 2020 05:19:26

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:19:19', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '44622ff5-6090-4329-8c39-42034595c755'	System	15 Oct 2020 05:19:26
User entered '15 Oct 2020 01:19'	System	15 Oct 2020 05:19:26

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 3'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 17:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:41:17', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8db46d92-9270-4bf0-a102-a99019109a11'	System	15 Oct 2020 22:41:39
User entered 'Yes (Y)'	System	15 Oct 2020 22:41:39

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 17:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:41:26', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8db46d92-9270-4bf0-a102-a99019109a11'	System	15 Oct 2020 22:41:39
User entered '98.5'	System	15 Oct 2020 22:41:39

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:41:29', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8db46d92-9270-4bf0-a102-a99019109a11'	System	15 Oct 2020 22:41:39
User entered 'No (N)'	System	15 Oct 2020 22:41:39

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:41:34', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8db46d92-9270-4bf0-a102-a99019109a11'	System	15 Oct 2020 22:41:39
User entered '15 Oct 2020 18:41'	System	15 Oct 2020 22:41:39

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 4'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 17:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:03', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '2ef564fb-b560-4122-a632-5f83fb1ed556'	System	16 Oct 2020 21:22:28
User entered 'Yes (Y)'	System	16 Oct 2020 21:22:28

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 17:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:19', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '2ef564fb-b560-4122-a632-5f83fb1ed556'	System	16 Oct 2020 21:22:28
User entered '98.3'	System	16 Oct 2020 21:22:28

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:22', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '2ef564fb-b560-4122-a632-5f83fb1ed556'	System	16 Oct 2020 21:22:28
User entered 'No (N)'	System	16 Oct 2020 21:22:28

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:27', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '2ef564fb-b560-4122-a632-5f83fb1ed556'	System	16 Oct 2020 21:22:28
User entered '16 Oct 2020 17:22'	System	16 Oct 2020 21:22:28

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 5'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 17:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:18:26', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0c64c2ec-7c16-41df-adf6-f4145604ab90'	System	18 Oct 2020 05:18:43
User entered 'Yes (Y)'	System	18 Oct 2020 05:18:43

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 17:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:18:33', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0c64c2ec-7c16-41df-adf6-f4145604ab90'	System	18 Oct 2020 05:18:43
User entered '98.3'	System	18 Oct 2020 05:18:43

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:18:36', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0c64c2ec-7c16-41df-adf6-f4145604ab90'	System	18 Oct 2020 05:18:43
User entered 'No (N)'	System	18 Oct 2020 05:18:43

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:18:40', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0c64c2ec-7c16-41df-adf6-f4145604ab90'	System	18 Oct 2020 05:18:43
User entered '18 Oct 2020 01:18'	System	18 Oct 2020 05:18:43

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 6'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 17:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:00:57', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f85996d6-cdff-49f6-8e06-3b6c242dece5'	System	19 Oct 2020 04:01:16
User entered 'Yes (Y)'	System	19 Oct 2020 04:01:16

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 17:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f85996d6-cdff-49f6-8e06-3b6c242dece5'	System	19 Oct 2020 04:01:16
User entered '98.0'	System	19 Oct 2020 04:01:16

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:06', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f85996d6-cdff-49f6-8e06-3b6c242dece5'	System	19 Oct 2020 04:01:16
User entered 'No (N)'	System	19 Oct 2020 04:01:16

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:10', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f85996d6-cdff-49f6-8e06-3b6c242dece5'	System	19 Oct 2020 04:01:16
User entered '19 Oct 2020 00:01'	System	19 Oct 2020 04:01:16

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 7'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 17:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:52:28', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '19571973-cf46-48f7-b121-2aa6f5ee553b'	System	19 Oct 2020 21:52:47
User entered 'Yes (Y)'	System	19 Oct 2020 21:52:47

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 17:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:52:33', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '19571973-cf46-48f7-b121-2aa6f5ee553b'	System	19 Oct 2020 21:52:47
User entered '98.0'	System	19 Oct 2020 21:52:47

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:52:36', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '19571973-cf46-48f7-b121-2aa6f5ee553b'	System	19 Oct 2020 21:52:47
User entered 'No (N)'	System	19 Oct 2020 21:52:47

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:52:41', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '19571973-cf46-48f7-b121-2aa6f5ee553b'	System	19 Oct 2020 21:52:47
User entered '19 Oct 2020 17:52'	System	19 Oct 2020 21:52:47

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-13T11:46:31', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '38ee3a68-e548-4f53-843c-f2a6b685ee8a'	System	13 Oct 2020 15:46:57
User entered 'None (1)'	System	13 Oct 2020 15:46:57

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:34', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '38ee3a68-e548-4f53-843c-f2a6b685ee8a'	System	13 Oct 2020 15:46:57
User entered 'No (N)'	System	13 Oct 2020 15:46:57

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:36', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '38ee3a68-e548-4f53-843c-f2a6b685ee8a'	System	13 Oct 2020 15:46:57
User entered 'No (N)'	System	13 Oct 2020 15:46:57

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-13T11:46:39', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '38ee3a68-e548-4f53-843c-f2a6b685ee8a'	System	13 Oct 2020 15:46:57
User entered 'None (1)'	System	13 Oct 2020 15:46:57

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:44', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '38ee3a68-e548-4f53-843c-f2a6b685ee8a'	System	13 Oct 2020 15:46:57
User entered '13 Oct 2020 11:46'	System	13 Oct 2020 15:46:57

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:32'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:02'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-13T21:49:40', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'faaee05b-8ad2-4992-b35f-7c5e7a45e025'	System	14 Oct 2020 01:50:01
User entered 'Does not interfere with activity (2)'	System	14 Oct 2020 01:50:01

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:43', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'faaee05b-8ad2-4992-b35f-7c5e7a45e025'	System	14 Oct 2020 01:50:01
User entered 'No (N)'	System	14 Oct 2020 01:50:01

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:47', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'faaee05b-8ad2-4992-b35f-7c5e7a45e025'	System	14 Oct 2020 01:50:01
User entered 'No (N)'	System	14 Oct 2020 01:50:01

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-13T21:49:50', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'faaee05b-8ad2-4992-b35f-7c5e7a45e025'	System	14 Oct 2020 01:50:01
User entered 'None (1)'	System	14 Oct 2020 01:50:01

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:57', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'faaee05b-8ad2-4992-b35f-7c5e7a45e025'	System	14 Oct 2020 01:50:01
User entered '13 Oct 2020 21:49'	System	14 Oct 2020 01:50:01

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:57'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 2'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-15T01:19:27', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '6daaee94-8aab-4467-a1ea-5c3640912cc0'	System	15 Oct 2020 05:19:52
User entered 'Does not interfere with activity (2)'	System	15 Oct 2020 05:19:52

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 17:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:19:30', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '6daaee94-8aab-4467-a1ea-5c3640912cc0'	System	15 Oct 2020 05:19:52
User entered 'No (N)'	System	15 Oct 2020 05:19:52

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:19:33', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '6daaee94-8aab-4467-a1ea-5c3640912cc0'	System	15 Oct 2020 05:19:52
User entered 'No (N)'	System	15 Oct 2020 05:19:52

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-15T01:19:37', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '6daaee94-8aab-4467-a1ea-5c3640912cc0'	System	15 Oct 2020 05:19:52
User entered 'None (1)'	System	15 Oct 2020 05:19:52

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:19:44', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '6daaee94-8aab-4467-a1ea-5c3640912cc0'	System	15 Oct 2020 05:19:52
User entered '15 Oct 2020 01:19'	System	15 Oct 2020 05:19:52

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 3'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-15T18:41:44', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1004268f-6d1f-460b-85af-7a380fd474ef'	System	15 Oct 2020 22:42:03
User entered 'Does not interfere with activity (2)'	System	15 Oct 2020 22:42:03

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 17:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:41:47', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1004268f-6d1f-460b-85af-7a380fd474ef'	System	15 Oct 2020 22:42:03
User entered 'No (N)'	System	15 Oct 2020 22:42:03

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:41:49', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1004268f-6d1f-460b-85af-7a380fd474ef'	System	15 Oct 2020 22:42:03
User entered 'No (N)'	System	15 Oct 2020 22:42:03

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-15T18:41:52', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1004268f-6d1f-460b-85af-7a380fd474ef'	System	15 Oct 2020 22:42:03
User entered 'None (1)'	System	15 Oct 2020 22:42:03

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:41:59', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1004268f-6d1f-460b-85af-7a380fd474ef' User entered '15 Oct 2020 18:41'	System	15 Oct 2020 22:42:03

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 4'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-16T17:22:33', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7adb04e-e08d-49fa-8f99-f39e319be147'	System	16 Oct 2020 21:22:48
User entered 'None (1)'	System	16 Oct 2020 21:22:48

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 17:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:35', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7adb04e-e08d-49fa-8f99-f39e319be147'	System	16 Oct 2020 21:22:48
User entered 'No (N)'	System	16 Oct 2020 21:22:48

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:37', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7adb04e-e08d-49fa-8f99-f39e319be147'	System	16 Oct 2020 21:22:48
User entered 'No (N)'	System	16 Oct 2020 21:22:48

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-16T17:22:40', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7adb04e-e08d-49fa-8f99-f39e319be147'	System	16 Oct 2020 21:22:48
User entered 'None (1)'	System	16 Oct 2020 21:22:48

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:45', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7adb04e-e08d-49fa-8f99-f39e319be147'	System	16 Oct 2020 21:22:48
User entered '16 Oct 2020 17:22'	System	16 Oct 2020 21:22:48

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 5'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-18T01:18:45', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4c8c1ef4-211b-4c66-9e69-c76ee5388d53'	System	18 Oct 2020 05:19:01
User entered 'None (1)'	System	18 Oct 2020 05:19:01

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 17:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:18:48', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4c8c1ef4-211b-4c66-9e69-c76ee5388d53'	System	18 Oct 2020 05:19:01
User entered 'No (N)'	System	18 Oct 2020 05:19:01

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:18:50', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4c8c1ef4-211b-4c66-9e69-c76ee5388d53'	System	18 Oct 2020 05:19:01
User entered 'No (N)'	System	18 Oct 2020 05:19:01

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-18T01:18:53', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4c8c1ef4-211b-4c66-9e69-c76ee5388d53'	System	18 Oct 2020 05:19:01
User entered 'None (1)'	System	18 Oct 2020 05:19:01

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:18:58', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4c8c1ef4-211b-4c66-9e69-c76ee5388d53'	System	18 Oct 2020 05:19:01
User entered '18 Oct 2020 01:18'	System	18 Oct 2020 05:19:01

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 6'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-19T00:01:15', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e230fa24-455c-410e-938b-0db7baada42d'	System	19 Oct 2020 04:01:31
User entered 'None (1)'	System	19 Oct 2020 04:01:31

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 17:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:18', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e230fa24-455c-410e-938b-0db7baada42d'	System	19 Oct 2020 04:01:31
User entered 'No (N)'	System	19 Oct 2020 04:01:31

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:20', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e230fa24-455c-410e-938b-0db7baada42d'	System	19 Oct 2020 04:01:31
User entered 'No (N)'	System	19 Oct 2020 04:01:31

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-19T00:01:22', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e230fa24-455c-410e-938b-0db7baada42d'	System	19 Oct 2020 04:01:31
User entered 'None (1)'	System	19 Oct 2020 04:01:31

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:27', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e230fa24-455c-410e-938b-0db7baada42d'	System	19 Oct 2020 04:01:31
User entered '19 Oct 2020 00:01'	System	19 Oct 2020 04:01:31

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 7'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-19T17:52:46', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7f62f7c-8d9f-4c54-9770-49f0f51cc78a'	System	19 Oct 2020 21:53:06
User entered 'None (1)'	System	19 Oct 2020 21:53:06

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 17:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:52:49', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7f62f7c-8d9f-4c54-9770-49f0f51cc78a'	System	19 Oct 2020 21:53:06
User entered 'No (N)'	System	19 Oct 2020 21:53:06

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:52:51', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7f62f7c-8d9f-4c54-9770-49f0f51cc78a'	System	19 Oct 2020 21:53:06
User entered 'No (N)'	System	19 Oct 2020 21:53:06

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-19T17:52:53', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7f62f7c-8d9f-4c54-9770-49f0f51cc78a'	System	19 Oct 2020 21:53:06
User entered 'None (1)'	System	19 Oct 2020 21:53:06

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 17:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:52:58', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7f62f7c-8d9f-4c54-9770-49f0f51cc78a'	System	19 Oct 2020 21:53:06
User entered '19 Oct 2020 17:52'	System	19 Oct 2020 21:53:06

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:49', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'db1540b6-ea72-4067-9e43-a74e6370d4db'	System	13 Oct 2020 15:47:12
User entered 'None (0)'	System	13 Oct 2020 15:47:12

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:51', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'db1540b6-ea72-4067-9e43-a74e6370d4db'	System	13 Oct 2020 15:47:12
User entered 'None (0)'	System	13 Oct 2020 15:47:12

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:53', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'db1540b6-ea72-4067-9e43-a74e6370d4db'	System	13 Oct 2020 15:47:12
User entered 'None (0)'	System	13 Oct 2020 15:47:12

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:56', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'db1540b6-ea72-4067-9e43-a74e6370d4db'	System	13 Oct 2020 15:47:12
User entered 'None (0)'	System	13 Oct 2020 15:47:12

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:58', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'db1540b6-ea72-4067-9e43-a74e6370d4db'	System	13 Oct 2020 15:47:12
User entered 'None (0)'	System	13 Oct 2020 15:47:12

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:47:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'db1540b6-ea72-4067-9e43-a74e6370d4db'	System	13 Oct 2020 15:47:12
User entered 'None (0)'	System	13 Oct 2020 15:47:12

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-13T11:47:04', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'db1540b6-ea72-4067-9e43-a74e6370d4db'	System	13 Oct 2020 15:47:12
User entered 'No (N)'	System	13 Oct 2020 15:47:12

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:47:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'db1540b6-ea72-4067-9e43-a74e6370d4db'	System	13 Oct 2020 15:47:12
User entered '13 Oct 2020 11:47'	System	13 Oct 2020 15:47:12

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:32'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:02'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:48:54', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1cf10a93-8271-4d5e-b6f1-793c80818f9a'	System	14 Oct 2020 01:49:37
User entered 'None (0)'	System	14 Oct 2020 01:49:37

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:48:57', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1cf10a93-8271-4d5e-b6f1-793c80818f9a'	System	14 Oct 2020 01:49:37
User entered 'None (0)'	System	14 Oct 2020 01:49:37

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1cf10a93-8271-4d5e-b6f1-793c80818f9a'	System	14 Oct 2020 01:49:37
User entered 'None (0)'	System	14 Oct 2020 01:49:37

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:03', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1cf10a93-8271-4d5e-b6f1-793c80818f9a'	System	14 Oct 2020 01:49:37
User entered 'None (0)'	System	14 Oct 2020 01:49:37

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1cf10a93-8271-4d5e-b6f1-793c80818f9a'	System	14 Oct 2020 01:49:37
User entered 'None (0)'	System	14 Oct 2020 01:49:37

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:10', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1cf10a93-8271-4d5e-b6f1-793c80818f9a'	System	14 Oct 2020 01:49:37
User entered 'None (0)'	System	14 Oct 2020 01:49:37

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-13T21:49:14', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1cf10a93-8271-4d5e-b6f1-793c80818f9a'	System	14 Oct 2020 01:49:37
User entered 'No (N)'	System	14 Oct 2020 01:49:37

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:21', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1cf10a93-8271-4d5e-b6f1-793c80818f9a'	System	14 Oct 2020 01:49:37
User entered '13 Oct 2020 21:49'	System	14 Oct 2020 01:49:37

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:57'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 2'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:19:54', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '7ad2a0b5-7669-4e7e-8ae9-3c054e407ba0'	System	15 Oct 2020 05:20:28
User entered 'None (0)'	System	15 Oct 2020 05:20:28

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:19:58', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '7ad2a0b5-7669-4e7e-8ae9-3c054e407ba0'	System	15 Oct 2020 05:20:28
User entered 'None (0)'	System	15 Oct 2020 05:20:28

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:20:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '7ad2a0b5-7669-4e7e-8ae9-3c054e407ba0'	System	15 Oct 2020 05:20:28
User entered 'None (0)'	System	15 Oct 2020 05:20:28

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:20:03', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '7ad2a0b5-7669-4e7e-8ae9-3c054e407ba0'	System	15 Oct 2020 05:20:28
User entered 'None (0)'	System	15 Oct 2020 05:20:28

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:20:05', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '7ad2a0b5-7669-4e7e-8ae9-3c054e407ba0'	System	15 Oct 2020 05:20:28
User entered 'None (0)'	System	15 Oct 2020 05:20:28

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:20:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '7ad2a0b5-7669-4e7e-8ae9-3c054e407ba0'	System	15 Oct 2020 05:20:28
User entered 'None (0)'	System	15 Oct 2020 05:20:28

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-15T01:20:11', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '7ad2a0b5-7669-4e7e-8ae9-3c054e407ba0'	System	15 Oct 2020 05:20:28
User entered 'No (N)'	System	15 Oct 2020 05:20:28

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:20:22', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '7ad2a0b5-7669-4e7e-8ae9-3c054e407ba0'	System	15 Oct 2020 05:20:28
User entered '15 Oct 2020 01:20'	System	15 Oct 2020 05:20:28

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 3'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:42:11', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f7bed483-a88f-4499-abe8-fa77447fb8e4'	System	16 Oct 2020 19:24:32
User entered 'None (0)'	System	16 Oct 2020 19:24:32

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:42:17', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f7bed483-a88f-4499-abe8-fa77447fb8e4'	System	16 Oct 2020 19:24:32
User entered 'No interference with activity (1)'	System	16 Oct 2020 19:24:32

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:42:20', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f7bed483-a88f-4499-abe8-fa77447fb8e4'	System	16 Oct 2020 19:24:32
User entered 'None (0)'	System	16 Oct 2020 19:24:32

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:42:22', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f7bed483-a88f-4499-abe8-fa77447fb8e4'	System	16 Oct 2020 19:24:32
User entered 'None (0)'	System	16 Oct 2020 19:24:32

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:42:24', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f7bed483-a88f-4499-abe8-fa77447fb8e4'	System	16 Oct 2020 19:24:32
User entered 'None (0)'	System	16 Oct 2020 19:24:32

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:42:27', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f7bed483-a88f-4499-abe8-fa77447fb8e4'	System	16 Oct 2020 19:24:32
User entered 'None (0)'	System	16 Oct 2020 19:24:32

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-15T18:42:33', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f7bed483-a88f-4499-abe8-fa77447fb8e4'	System	16 Oct 2020 19:24:32
User entered 'No (N)'	System	16 Oct 2020 19:24:32

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:42:38', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f7bed483-a88f-4499-abe8-fa77447fb8e4'	System	16 Oct 2020 19:24:32
User entered '15 Oct 2020 18:42'	System	16 Oct 2020 19:24:32

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 4'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:49', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '54c2ab99-30ff-437e-99ea-40f3a354e0a9'	System	16 Oct 2020 21:23:10
User entered 'None (0)'	System	16 Oct 2020 21:23:10

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:51', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '54c2ab99-30ff-437e-99ea-40f3a354e0a9'	System	16 Oct 2020 21:23:10
User entered 'None (0)'	System	16 Oct 2020 21:23:10

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:53', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '54c2ab99-30ff-437e-99ea-40f3a354e0a9'	System	16 Oct 2020 21:23:10
User entered 'None (0)'	System	16 Oct 2020 21:23:10

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:55', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '54c2ab99-30ff-437e-99ea-40f3a354e0a9'	System	16 Oct 2020 21:23:10
User entered 'None (0)'	System	16 Oct 2020 21:23:10

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:57', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '54c2ab99-30ff-437e-99ea-40f3a354e0a9'	System	16 Oct 2020 21:23:10
User entered 'None (0)'	System	16 Oct 2020 21:23:10

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:59', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '54c2ab99-30ff-437e-99ea-40f3a354e0a9'	System	16 Oct 2020 21:23:10
User entered 'None (0)'	System	16 Oct 2020 21:23:10

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-16T17:23:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '54c2ab99-30ff-437e-99ea-40f3a354e0a9'	System	16 Oct 2020 21:23:10
User entered 'No (N)'	System	16 Oct 2020 21:23:10

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:23:07', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '54c2ab99-30ff-437e-99ea-40f3a354e0a9'	System	16 Oct 2020 21:23:10
User entered '16 Oct 2020 17:23'	System	16 Oct 2020 21:23:10

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 5'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:19:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0a903c1f-c779-499a-92eb-1ed96d3480d8'	System	18 Oct 2020 05:19:30
User entered 'None (0)'	System	18 Oct 2020 05:19:30

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:19:04', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0a903c1f-c779-499a-92eb-1ed96d3480d8'	System	18 Oct 2020 05:19:30
User entered 'None (0)'	System	18 Oct 2020 05:19:30

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:19:07', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0a903c1f-c779-499a-92eb-1ed96d3480d8'	System	18 Oct 2020 05:19:30
User entered 'None (0)'	System	18 Oct 2020 05:19:30

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:19:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0a903c1f-c779-499a-92eb-1ed96d3480d8'	System	18 Oct 2020 05:19:30
User entered 'None (0)'	System	18 Oct 2020 05:19:30

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:19:10', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0a903c1f-c779-499a-92eb-1ed96d3480d8'	System	18 Oct 2020 05:19:30
User entered 'None (0)'	System	18 Oct 2020 05:19:30

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:19:12', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0a903c1f-c779-499a-92eb-1ed96d3480d8'	System	18 Oct 2020 05:19:30
User entered 'None (0)'	System	18 Oct 2020 05:19:30

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-18T01:19:15', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0a903c1f-c779-499a-92eb-1ed96d3480d8'	System	18 Oct 2020 05:19:30
User entered 'No (N)'	System	18 Oct 2020 05:19:30

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:19:20', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0a903c1f-c779-499a-92eb-1ed96d3480d8'	System	18 Oct 2020 05:19:30
User entered '18 Oct 2020 01:19'	System	18 Oct 2020 05:19:30

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 6'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:31', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4d40998b-ef02-4065-b278-c7bdb928772f'	System	19 Oct 2020 04:01:58
User entered 'None (0)'	System	19 Oct 2020 04:01:58

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:38', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4d40998b-ef02-4065-b278-c7bdb928772f'	System	19 Oct 2020 04:01:58
User entered 'None (0)'	System	19 Oct 2020 04:01:58

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:40', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4d40998b-ef02-4065-b278-c7bdb928772f'	System	19 Oct 2020 04:01:58
User entered 'None (0)'	System	19 Oct 2020 04:01:58

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:41', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4d40998b-ef02-4065-b278-c7bdb928772f'	System	19 Oct 2020 04:01:58
User entered 'None (0)'	System	19 Oct 2020 04:01:58

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:43', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4d40998b-ef02-4065-b278-c7bdb928772f'	System	19 Oct 2020 04:01:58
User entered 'None (0)'	System	19 Oct 2020 04:01:58

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:45', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4d40998b-ef02-4065-b278-c7bdb928772f'	System	19 Oct 2020 04:01:58
User entered 'None (0)'	System	19 Oct 2020 04:01:58

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-19T00:01:49', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4d40998b-ef02-4065-b278-c7bdb928772f'	System	19 Oct 2020 04:01:58
User entered 'No (N)'	System	19 Oct 2020 04:01:58

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:54', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4d40998b-ef02-4065-b278-c7bdb928772f' User entered '19 Oct 2020 00:01'	System	19 Oct 2020 04:01:58
	System	19 Oct 2020 04:01:58

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 7'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:53:03', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afb2e1a0-1682-42b1-a4f6-49c0a3bc2977'	System	19 Oct 2020 21:53:27
User entered 'None (0)'	System	19 Oct 2020 21:53:27

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:53:05', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afb2e1a0-1682-42b1-a4f6-49c0a3bc2977'	System	19 Oct 2020 21:53:27
User entered 'None (0)'	System	19 Oct 2020 21:53:27

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:53:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afb2e1a0-1682-42b1-a4f6-49c0a3bc2977'	System	19 Oct 2020 21:53:27
User entered 'None (0)'	System	19 Oct 2020 21:53:27

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:53:10', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afb2e1a0-1682-42b1-a4f6-49c0a3bc2977'	System	19 Oct 2020 21:53:27
User entered 'None (0)'	System	19 Oct 2020 21:53:27

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:53:11', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afb2e1a0-1682-42b1-a4f6-49c0a3bc2977'	System	19 Oct 2020 21:53:27
User entered 'None (0)'	System	19 Oct 2020 21:53:27

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:53:13', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afb2e1a0-1682-42b1-a4f6-49c0a3bc2977'	System	19 Oct 2020 21:53:27
User entered 'None (0)'	System	19 Oct 2020 21:53:27

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

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 (390c60986467e739)', Time: '2020-10-19T17:53:17', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afb2e1a0-1682-42b1-a4f6-49c0a3bc2977'	System	19 Oct 2020 21:53:27
User entered 'No (N)'	System	19 Oct 2020 21:53:27

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:53:23', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afb2e1a0-1682-42b1-a4f6-49c0a3bc2977'	System	19 Oct 2020 21:53:27
User entered '19 Oct 2020 17:53'	System	19 Oct 2020 21:53:27

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 17:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melissa Andrasko (b) (4)	22 Oct 2020 18:55:44

US3802218

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Melissa Andrasko (b) (4)	22 Oct 2020 18:55:44

US3802218

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	Melissa Andrasko (b) (4)	22 Oct 2020 18:55:44

US3802218

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Contact attempted on 10/20,10/21,10/22.'	Melissa Andrasko (b) (4)	22 Oct 2020 18:55:44

US3802218

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melissa Andrasko (b) (4)	22 Oct 2020 18:55:50

US3802218

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 18:55:50

US3802218

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melissa Andrasko (b) (4)	28 Oct 2020 15:10:20

US3802218

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 09:04:20
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	Melissa Andrasko (b) (4)	28 Oct 2020 15:14:11
answered with 'updated' (Site from System).		
User entered '26 Oct 2020' reason for change: Data Entry Error	Melissa Andrasko (b) (4)	28 Oct 2020 15:13:32
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Oct 2020 15:10:20
User entered '23 Oct 2020'	Melissa Andrasko (b) (4)	28 Oct 2020 15:10:20

US3802218

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	Melissa Andrasko (b) (4)	28 Oct 2020 15:10:20

US3802218

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Attempted to contact participant 3 times without success'	Melissa Andrasko (b) (4)	28 Oct 2020 15:10:20

US3802218

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melissa Andrasko (b) (4)	28 Oct 2020 15:14:31

US3802218

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 15:14:31

US3802218

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	05 Nov 2020 18:33:34

US3802218

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '6 Nov 2020' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	06 Nov 2020 20:26:39
User entered '5 Nov 2020'	Lalicia Roman (b) (4)	05 Nov 2020 18:33:34

US3802218

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	06 Nov 2020 20:26:39
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lalicia Roman (b) (4)	05 Nov 2020 18:33:34

US3802218

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 17:01:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Jennifer Nagg (b) (4)	06 Nov 2020 20:26:39
User entered 'contact attempted 3x'	Lalicia Roman (b) (4)	05 Nov 2020 18:33:34

US3802218

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	05 Nov 2020 18:33:39

US3802218

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 18:33:39

US3802218

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:23

US3802218

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:23

US3802218

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:23

US3802218

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 17:01:20

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	12 Nov 2020 15:58:23

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '10:10'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '12 Nov 2020 10:10'	System	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.3' F	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Infrared'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '89'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User closed query '	(b) (4), (b) (6)	24 Nov 2020 18:51:15

Per CDM: Respiratory rate >16 and ≤20 per CCG v2.0 considered grade 1. Please indicate if CS/NCS and report as AE, if appropriate.

' (Site from DM).

Query '

Dominic Kramer (b) (4) 24 Nov 2020 16:17:37
(b) (4)

Per CDM: Respiratory rate >16 and ≤20 per CCG v2.0 considered grade 1. Please indicate if CS/NCS and report as AE, if appropriate.

' answered with 'Value is in Range. NCS' (Site from DM).

User opened query '

(b) (4), (b) (6) 24 Nov 2020 12:17:04
(b) (4)

Per CDM: Respiratory rate >16 and ≤20 per CCG v2.0 considered grade 1. Please indicate if CS/NCS and report as AE, if appropriate.

' (Site from DM).

User entered '18'

Emily Carney (b) (4) 12 Nov 2020 15:58:48
(b) (4)

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Per CDM: Systolic Blood Pressure >150 and ≤155 per CCG v2.0 considered grade 2. Please indicate if CS/NCS and report as AE, if appropriate' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 18:51:52
Query 'Per CDM: Systolic Blood Pressure >150 and ≤155 per CCG v2.0 considered grade 2. Please indicate if CS/NCS and report as AE, if appropriate' answered with 'Hypertension reported in med history. NCS' (Site from DM).	Dominic Kramer (b) (4)	24 Nov 2020 16:18:18
User opened query 'Per CDM: Systolic Blood Pressure >150 and ≤155 per CCG v2.0 considered grade 2. Please indicate if CS/NCS and report as AE, if appropriate' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 12:17:28
User entered '154'	Emily Carney (b) (4)	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '88'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 17:01:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 17:01:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:53

US3802218

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 17:01:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:53

US3802218

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 17:01:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:59:02

US3802218

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 17:01:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:59:02

US3802218

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '10:51'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:59:02

US3802218

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '12 Nov 2020 10:51'	System	12 Nov 2020 15:59:02

US3802218

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:59:05

US3802218

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 17:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 15:59:05

US3802218

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 64'	System	11 Sep 2020 14:49:41

US3802218

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[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 (390c60986467e739)', Time: '2020-11-12T18:28:55', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '67c68bb4-ae32-4f06-b894-0a7d322ea96e'	System	12 Nov 2020 23:29:17
User entered 'No (N)'	System	12 Nov 2020 23:29:17

US3802218

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

Have you been exposed to someone with 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 (390c60986467e739)', Time: '2020-11-12T18:29:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '67c68bb4-ae32-4f06-b894-0a7d322ea96e'	System	12 Nov 2020 23:29:17
User entered 'No (N)'	System	12 Nov 2020 23:29:17

US3802218

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-11-12T18:29:12', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '67c68bb4-ae32-4f06-b894-0a7d322ea96e'	System	12 Nov 2020 23:29:17
User entered '12 Nov 2020 18:29:12'	System	12 Nov 2020 23:29:17

US3802218

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 14:49:41

US3802218

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 14:49:41
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '08 Nov 2020 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '12 Nov 2020 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '15 Nov 2020 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '19 Nov 2020 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[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 (390c60986467e739)', Time: '2020-11-23T23:56:42', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0b3ec151-17d1-46e4-9a07-c32c0e35db10'	System	24 Nov 2020 04:56:59
User entered 'No (N)'	System	24 Nov 2020 04:56:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Have you been exposed to someone with 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 (390c60986467e739)', Time: '2020-11-23T23:56:49', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0b3ec151-17d1-46e4-9a07-c32c0e35db10'	System	24 Nov 2020 04:56:59
User entered 'No (N)'	System	24 Nov 2020 04:56:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-11-23T23:56:54', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0b3ec151-17d1-46e4-9a07-c32c0e35db10'	System	24 Nov 2020 04:56:59
User entered '23 Nov 2020 23:56:54'	System	24 Nov 2020 04:56:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:33:29

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 17:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 17:01:20

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:18:08
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	02 Nov 2020 21:07:24
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:23:46
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:23:40
User entered 'USA-US098-2020-mRNA-1273-P301000001'	System	03 Nov 2020 17:23:09
User entered 'New'	(b) (4), (b) (6)	03 Nov 2020 17:23:09

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV Query: Was this event considered a worsening of the subjects medical history paraoesophageal hernia. If so, please consider updating the event term to reflect the worsening of paraoesophageal hiatal hernia. If not please explain.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:12:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:00:48
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Paraesophageal hiatal hernia - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 22:06:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	16 Nov 2020 22:06:48
Data point term sent to Coder	System	15 Nov 2020 13:05:04
DataPoint Un-verified.	Jennifer Nagg (b) (4)	15 Nov 2020 13:04:37
Coding entries removed.	(b) (4)	15 Nov 2020 13:04:37
User entered 'PARAESOPHOGEAL HIATAL HERNIA worsening' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	15 Nov 2020 13:04:37
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Paraesophageal hiatal hernia - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 23:50:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	12 Nov 2020 23:50:39
User opened query 'PV Query: Was this event considered a worsening of the subjects medical history paraoesophageal hernia. If so, please consider updating the event term to reflect the worsening of paraoesophageal hiatal hernia. If not please explain.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 13:42:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:09:51
Data point term sent to Coder	System	11 Nov 2020 13:27:06

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'CDM coding: Kindly update the term if it means 'Paraesophageal hiatal hernia', else please clarify' (Site from System).	System	11 Nov 2020 13:26:47
Query 'CDM coding: Kindly update the term if it means 'Paraesophageal hiatal hernia', else please clarify' answered with 'updated' (Site from System).	Lalicia Roman (b) (4)	11 Nov 2020 13:26:47
DataPoint Un-verified.	(b) (4)	
	Lalicia Roman (b) (4)	11 Nov 2020 13:26:17
	(b) (4)	
User entered 'PARAESOPHOGEAL Hiatal hernia' reason for change: Data Entry Error	Lalicia Roman (b) (4)	11 Nov 2020 13:26:17
	(b) (4)	
User opened query 'CDM coding: Kindly update the term if it means 'Paraesophageal hiatal hernia', else please clarify' (Site from System).	Coder Import (b) (4)	11 Nov 2020 06:18:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:08:29
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 15:05:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:20:10
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
Data point term sent to Coder	System	02 Nov 2020 21:09:56
User entered 'Hernia, paraesophageal repair'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:20:14
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:20:16
User entered 'No (N)'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:20:18
User entered 'No (N)'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: It was reported since Sept 2020 the subject was experiencing worsening symptoms including postprandial epigastric pain and dysphagia. Please consider updating the start date of the event to when the signs and symptoms started.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:14:14
User closed query 'PV Query: It was reported since Sept 2020 the subject was experiencing worsening symptoms including postprandial epigastric pain and dysphagia. Please consider updating the start date of the event to when the signs and symptoms started.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 14:54:42
Query 'PV Query: It was reported since Sept 2020 the subject was experiencing worsening symptoms including postprandial epigastric pain and dysphagia. Please consider updating the start date of the event to when the signs and symptoms started.' answered with 'this was a scheduled surgery' (Site from Safety).	Jennifer Nagg (b) (4)	15 Nov 2020 13:02:33
User opened query 'PV Query: It was reported since Sept 2020 the subject was experiencing worsening symptoms including postprandial epigastric pain and dysphagia. Please consider updating the start date of the event to when the signs and symptoms started.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 13:42:58
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:20:21
User entered '28 Oct 2020'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:36:19
User entered empty.	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:09:03
DataPoint Un-verified.	Lalicia Roman (b) (4)	11 Nov 2020 13:26:17
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lalicia Roman (b) (4)	11 Nov 2020 13:26:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:20:25
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:09:05
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	11 Nov 2020 13:26:39
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	11 Nov 2020 13:26:39
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	11 Nov 2020 13:26:17
DataPoint Un-verified.	Lalicia Roman (b) (4)	11 Nov 2020 13:26:17
	(b) (4)	
User entered '5 Nov 2020' reason for change: Data Entry Error	Lalicia Roman (b) (4)	11 Nov 2020 13:26:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:20:33
User entered empty.	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:20:35
User entered empty.	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Severity](#)

Audit	User	Time (GMT)
User closed query 'Grade not recorded in SAE event form. please confirm source of this data . ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 19:09:21
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:09:17
Query 'Grade not recorded in SAE event form. please confirm source of this data . ' answered with 'Recorded on form' (Site from CRA).	Jennifer Nagg (b) (4)	09 Nov 2020 01:00:46
User opened query 'Grade not recorded in SAE event form. please confirm source of this data . ' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 16:28:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:20:43
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:12
User entered '0'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:15
User entered '0'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Thanks for updating information Kindly update Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile. Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:40:10
Query 'Per CDM: Thanks for updating information Kindly update Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile. Thank you!' answered with 'done' (Site from DM).	Jennifer Nagg (b) (4)	10 Nov 2020 20:51:21
User opened query 'Per CDM: Thanks for updating information Kindly update Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile. Thank you!' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:52:17
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)	09 Nov 2020 09:51:16
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:31
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 'hospital admission date is recorded, subject is still hospitalized' (Site from System).	Jennifer Nagg (b) (4)	02 Nov 2020 21:11:07
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	02 Nov 2020 21:09:08
User entered '1'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:29
User entered '28 Oct 2020'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:09:30
DataPoint Un-verified.	Jennifer Nagg (b) (4)	10 Nov 2020 20:51:12
	(b) (4)	
User entered '5 Nov 2020' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	10 Nov 2020 20:51:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:35
User entered empty.	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:36
User entered 'No (N)'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:38
User entered empty.	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:42
User entered '0'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:44
User entered '0'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:46
User entered '0'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:49
User entered 'Not Related (NOT RELATED)'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:51
User entered 'Not Related (NOT RELATED)'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

Action taken with investigational product

Audit	User	Time (GMT)
Query 'PV Query: As the event occurred after the second dose of the study drug, please update the action taken with study drug from none to not applicable.' canceled (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:13:40
	(b) (4), (b) (6)	18 Nov 2020 15:49:21
DataPoint Un-verified.	Jennifer Nagg (b) (4)	15 Nov 2020 13:04:37
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	15 Nov 2020 13:04:37
User opened query 'PV Query: As the event occurred after the second dose of the study drug, please update the action taken with study drug from none to not applicable.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 13:40:38
	(b) (4), (b) (6)	03 Nov 2020 16:21:53
User entered 'None (NONE)'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:55
User entered '0'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:59
User entered '1'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:22:01
User entered '1'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:09:36
DataPoint Un-verified.	Lalicia Roman (b) (4)	11 Nov 2020 13:26:39
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Lalicia Roman (b) (4)	11 Nov 2020 13:26:39
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:22:03
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:35:48
User entered empty.	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Narrative](#)

Audit	User	Time (GMT)
User entered '10/28/2020-ADMITTED PRIOR TO SURGERY-PAST MEDICAL HISTORY REPORT OF KNOWN PARAESOPHAGEAL HERNIA THAT HAS BEEN EXPERIENCING WORSENING SYMPTOMS. ADMITTED FOR A LAPAROSCOPIC REPAIR OF HERNIA. CXR: CARDIOMEDIASTINAL SILHOUETTE NOT ENLARGED, INCLUDING HIATAL HERNIA, PULMONARY VASCULAR MARKINGS NOT ENLARGED, LUNG VOLUMES NORMAL, NO FOCAL CONSOLIDATION, PLEURAL EFFUSION OR SIGNIFICANT PNEUMOTHORAX. NO ACUTE OSSEOUS OR SOFT TISSUE ABNORMALITIES 10/29/2020- VS 37.0, 97/62, 76, 16, 93%, 108KG, 34.9BMI 10/30/2020- REPAIR HIATAL HERNIA LAPROSCOPIC, ESOPHOGOSCOPY, GASTROPEXY, ESTIMATED BLOOD LOSS 10ML, FINDINGS: GIANT PARAESOPHOGEAL HERNIA WITH MAJORITY OF STOMACH INTRATHORACIC LAP GPEH REPAIR WITH GASTROPEXY, HIATAL CLOSURE WITH 2 POSTERIOR STITCHES AND 3 STITCHES AT 3:00, LEFT PIGTAIL. VS 36.6, 115/60, 84, 16, 97% 10/31/2020- NO ACUTE EVENTS OVERNIGHT, ADEQUATE PAIN CONTROL. CXR: SMALL AMOUNT OF LEFT SUBPULMONIC EFFUSION LEFT PIGTAIL CATHETER REMAINS IN PLACE. 11/1/2020- VS 37.5, 84/52, 64, 17, 95%, CONTINUE INPATIENT CARE' (WR#5168263)	System	26 Nov 2020 16:58:05
User opened query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 13:43:12
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 13:41:08
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:35:44

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Nov 2020 21:12:04
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	02 Nov 2020 21:12:04
User entered '10/28/2020-Admitted prior to surgery-Past medical history report of known paraesophageal hernia that has been experiencing worsening symptoms. Admitted for a laparoscopic repair of hernia. CXR: cardiomeastinal silhouette not enlarged, including hiatal hernia, Pulmonary vascular markings not enlarged, lung volumes normal, no focal consolidation, pleural effusion or significant pneumothorax. No acute osseous or soft tissue abnormalities 10/29/2020- VS 37.0, 97/62, 76, 16, 93%, 108kg, 34.9BMI 10/30/2020- Repair hiatal hernia laproscopic, esophogoscopy, gastropexy, estimated blood loss 10ml, findings: giant paraesophageal hernia with majority of stomach intrathoracic lap GPEH repair with gastropexy, hiatal closure with 2 posterior stitches and 3 stitches at 3:00, left pigtail. VS 36.6, 115/60, 84, 16, 97% 10/31/2020- no acute events overnight, adequate pain control. CXR: small amount of left subpulmonic effusion left pigtail catheter remains in place. 11/1/2020- VS 37.5, 84/52, 64, 17, 95%, continue inpatient care' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:12:04
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Nov 2020 21:09:08
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
User entered '0'	System	02 Nov 2020 21:09:08

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 17:01:20

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:36:46
User entered 'Yes (Y)'	Lalicia Roman (b) (4)	11 Sep 2020 14:51:25
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:14:45
User closed query 'Please update Medication name to Triumeq' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 04:29:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: ABACAVIR SULFATE;DOLUTEGRAVIR SODIUM;LAMIVUDINE, PRODUCTSYNONYM: TRIUMEQ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 01:48:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 01:48:28
Data point term sent to Coder	System	04 Nov 2020 01:47:29
Query 'Please update Medication name to Triumeq' answered with 'Done' (Site from CRA).	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 01:46:49
Coding entries removed.	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 01:46:42
User entered 'TRIumeq' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 01:46:42
User opened query 'Please update Medication name to Triumeq' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 16:42:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: ABACAVIR SULFATE;DOLUTEGRAVIR SODIUM;LAMIVUDINE, PRODUCTSYNONYM: TRIUMEQ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 10:25:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 10:25:55
Data point term sent to Coder	System	11 Sep 2020 14:52:53

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Triameq'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:52:25

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:42:22
User entered 'No (N)'	Lalicia Roman (b) (4)	11 Sep 2020 14:52:25
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:42:34
User entered 'HIV'	Lalicia Roman (b) (4)	11 Sep 2020 14:52:25
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'please update to 950 as noted in source. thank you' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:10:30
User opened query 'Per CDM: Site response noted; however, "Dose per administration" = "1" and "Dose unit" = "1 TABLET CONTAINS: 600 MG OF ABACAVIR, 50 MG OF DOLUTEGRAVIR, AND 300 MG OF LAMIVUDINE". Please update the dose unit to "mg" and the "Dose per administration" = "600/50/300". Please review and reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:18:58
User closed query 'Per DM CLR: Please note, this is a combination drug; however, the total component has been reported in the dose field. Please update the dose to include all components as applicable (e.g., 50/600/300).' ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:18:58
User entered '1' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	15 Nov 2020 12:54:26
User entered '600 MG OF ABACAVIR, 50 MG OF DOLUTEGRAVIR, AND 300 MG OF LAMIVUDINE' (non-conformant).	Lalicia Roman (b) (4)	13 Nov 2020 19:08:32
Query 'Per DM CLR: Please note, this is a combination drug; however, the total component has been reported in the dose field. Please update the dose to include all components as applicable (e.g., 50/600/300).' ' answered with 'updated' ' (Site from DM).	Lalicia Roman (b) (4)	13 Nov 2020 16:41:16
DataPoint Un-verified.	Lalicia Roman (b) (4)	13 Nov 2020 16:39:49
User entered '600 mg of abacavir, 50 mg of dolutegravir, and 300 mg of lamivudine.' (non-conformant).	Lalicia Roman (b) (4)	13 Nov 2020 16:39:49
User opened query 'Per DM CLR: Please note, this is a combination drug; however, the total component has been reported in the dose field. Please update the dose to include all components as applicable (e.g., 50/600/300).' ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:18:51

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:45:36
User entered '950'	Lalicia Roman (b) (4)	11 Sep 2020 14:52:25
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

[Dose unit](#)

Audit	User	Time (GMT)
User opened query 'Please update Dose Unit to "mg" (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:08:28
DataPoint Un-verified.	Jennifer Nagg (b) (4)	15 Nov 2020 12:54:26
User entered 'Other (OTHER)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	15 Nov 2020 12:54:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:45:43
User entered 'mg (mg)'	Lalicia Roman (b) (4)	11 Sep 2020 14:52:25

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:08:32
DataPoint Un-verified.	Jennifer Nagg (b) (4)	15 Nov 2020 12:54:26
	(b) (4)	
User entered '1 Tablet contains: 600 MG OF ABACAVIR, 50 MG OF DOLUTEGRAVIR, AND 300 MG OF LAMIVUDINE' reason for change:	Jennifer Nagg (b) (4)	15 Nov 2020 12:54:26
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:45:45
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:52:25
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:45:50
User entered 'once daily (QD)'	Lalicia Roman (b) (4)	11 Sep 2020 14:52:25
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:45:52
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:52:25
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:45:53
User entered 'Oral (ORAL)'	Lalicia Roman (b) (4)	11 Sep 2020 14:52:25
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:45:56
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:52:25
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:46:00
User entered 'UN UNK 2016'	Lalicia Roman (b) (4)	11 Sep 2020 14:52:25
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:46:02
User entered '0'	Lalicia Roman (b) (4)	11 Sep 2020 14:52:25
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:46:04
User entered 'Yes (Y)'	Lalicia Roman (b) (4)	11 Sep 2020 14:52:25
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:46:09
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:52:25
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:46:11
User entered 'No (N)'	Lalicia Roman (b) (4)	11 Sep 2020 14:52:25
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:52:25

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:52:25

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 14:52:25

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 01:48:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 01:48:28
Data point term sent to Coder Coding entries removed.	System Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 01:47:28 04 Nov 2020 01:47:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	03 Nov 2020 16:46:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 14:54:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 14:54:35
Data point term sent to Coder User entered 'lisinopril'	System Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:53:56 11 Sep 2020 14:53:14

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:46:55
User entered 'No (N)'	Lalicia Roman (b) (4)	11 Sep 2020 14:53:14
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:31:25
User closed query 'Hypertension is listed as the indication in source. please verify . ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 04:31:23
User closed query 'The Indication of Kidney Health is not listed in the Medical History Form. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 04:31:21
Query 'The Indication of Kidney Health is not listed in the Medical History Form. Please verify and reconcile.' answered with 'Updated' (Site from CRA).	Jennifer Nagg (b) (4)	04 Nov 2020 01:47:36
Query 'Hypertension is listed as the indication in source. please verify . ' answered with 'Done' (Site from CRA).	Jennifer Nagg (b) (4)	04 Nov 2020 01:47:29
User entered 'Hypertension' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	04 Nov 2020 01:47:21
User opened query 'Hypertension is listed as the indication in source. please verify . ' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 16:47:54
User opened query 'The Indication of Kidney Health is not listed in the Medical History Form. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 03:18:23
User entered 'kidney health'	Lalicia Roman (b) (4)	11 Sep 2020 14:53:14

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:48:02
User entered '5'	Lalicia Roman (b) (4)	11 Sep 2020 14:53:14
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:48:04
User entered 'mg (mg)'	Lalicia Roman (b) (4)	11 Sep 2020 14:53:14
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:48:05
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:53:14
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:48:09
User entered 'once daily (QD)'	Lalicia Roman (b) (4)	11 Sep 2020 14:53:14
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:48:11
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:53:14
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:48:15
User entered 'Oral (ORAL)'	Lalicia Roman (b) (4)	11 Sep 2020 14:53:14
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:48:17
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:53:14
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:48:19
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:53:14
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:48:24
User entered '1'	Lalicia Roman (b) (4)	11 Sep 2020 14:53:14
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:48:26
User entered 'Yes (Y)'	Lalicia Roman (b) (4)	11 Sep 2020 14:53:14
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:48:28
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:53:14
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:48:30
User entered 'No (N)'	Lalicia Roman (b) (4)	11 Sep 2020 14:53:14
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:53:14

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:53:14

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 14:53:14

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:48:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIMEPIRIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 14:55:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 14:55:39
Data point term sent to Coder	System	11 Sep 2020 14:55:00
User entered 'glimepiride'	Lalicia Roman (b) (4)	11 Sep 2020 14:54:10

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:48:51
User entered 'No (N)'	Lalicia Roman (b) (4)	11 Sep 2020 14:54:10
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:48:57
User closed query 'Diabetes Type 2 is not listed in Medical History form. Please verify and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	01 Nov 2020 15:18:49
Query 'Diabetes Type 2 is not listed in Medical History form. Please verify and reconcile. ' answered with 'diabetes type 2 is present on Med Hx' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 20:57:17
User opened query 'Diabetes Type 2 is not listed in Medical History form. Please verify and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 03:20:31
User entered 'diabetes type 2'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:54:10

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:48:59
User entered '1'	Lalicia Roman (b) (4)	11 Sep 2020 14:54:10
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:49:02
User entered 'mg (mg)'	Lalicia Roman (b) (4)	11 Sep 2020 14:54:10
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:49:05
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:54:10
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:49:07
User entered 'once daily (QD)'	Lalicia Roman (b) (4)	11 Sep 2020 14:54:10
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:49:10
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:54:10
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:49:12
User entered 'Oral (ORAL)'	Lalicia Roman (b) (4)	11 Sep 2020 14:54:10
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:49:17
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:54:10
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:49:19
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:54:10
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:49:25
User entered '1'	Lalicia Roman (b) (4)	11 Sep 2020 14:54:10
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:49:30
User entered 'Yes (Y)'	Lalicia Roman (b) (4)	11 Sep 2020 14:54:10
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:49:36
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:54:10
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:49:39
User entered 'No (N)'	Lalicia Roman (b) (4)	11 Sep 2020 14:54:10
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:54:10

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:54:10

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 14:54:10

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:42:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:42:27
Data point term sent to Coder Coding entries removed.	System Emily Dougherty (b) (4) (b) (4)	03 Nov 2020 18:41:42 03 Nov 2020 18:41:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	03 Nov 2020 16:50:33
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 14:56:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 14:56:46
Data point term sent to Coder User entered 'Tamsulosin'	System Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:08 11 Sep 2020 14:55:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:50:35
User entered 'No (N)'	Lalicia Roman (b) (4)	11 Sep 2020 14:55:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Indication is recorded as "Prostate". Please update the indication of this medication to also include the medical condition/ diagnosis for the given organs.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 05:17:37
	(b) (4), (b) (6)	03 Nov 2020 18:48:46
Query 'Per CDM: Indication is recorded as "Prostate". Please update the indication of this medication to also include the medical condition/ diagnosis for the given organs.' answered with 'updated' (Site from DM).	Emily Dougherty (b) (4)	03 Nov 2020 18:41:42
User entered 'Enlarged PROSTATE' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 18:41:37
User opened query 'Per CDM: Indication is recorded as "Prostate". Please update the indication of this medication to also include the medical condition/ diagnosis for the given organs.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 12:08:56
User entered 'prostate'	Lalicia Roman (b) (4)	11 Sep 2020 14:55:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:50:43
User entered '0.4'	Lalicia Roman (b) (4)	11 Sep 2020 14:55:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:50:45
User entered 'mg (mg)'	Lalicia Roman (b) (4)	11 Sep 2020 14:55:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:50:53
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:55:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:50:55
User entered 'once daily (QD)'	Lalicia Roman (b) (4)	11 Sep 2020 14:55:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:50:59
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:55:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:51:02
User entered 'Oral (ORAL)'	Lalicia Roman (b) (4)	11 Sep 2020 14:55:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:51:04
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:55:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:51:18
User entered 'UN UNK 2017'	Lalicia Roman (b) (4)	11 Sep 2020 14:55:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:51:16
User entered '0'	Lalicia Roman (b) (4)	11 Sep 2020 14:55:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:51:21
User entered 'Yes (Y)'	Lalicia Roman (b) (4)	11 Sep 2020 14:55:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:51:23
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:55:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:51:26
User entered 'No (N)'	Lalicia Roman (b) (4)	11 Sep 2020 14:55:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:55:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:55:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 14:55:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:07:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 14:56:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 14:56:46
Data point term sent to Coder	System	11 Sep 2020 14:56:11
User entered 'aspirin'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:05

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:12:16
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:19:21
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify ' answered with 'updated ' (Site from DM).	Lalicia Roman (b) (4) (b) (4)	13 Nov 2020 16:42:58
DataPoint Un-verified.	Lalicia Roman (b) (4) (b) (4)	13 Nov 2020 16:42:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Lalicia Roman (b) (4) (b) (4)	13 Nov 2020 16:42:46
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 02:33:36
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:07:34
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:05

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:07:36
User entered 'heart health'	Lalicia Roman (b) (4)	11 Sep 2020 14:56:05
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:07:39
User entered '81'	Lalicia Roman (b) (4)	11 Sep 2020 14:56:05
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:07:41
User entered 'mg (mg)'	Lalicia Roman (b) (4)	11 Sep 2020 14:56:05
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:07:43
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:56:05
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:07:45
User entered 'once daily (QD)'	Lalicia Roman (b) (4)	11 Sep 2020 14:56:05
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:07:50
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:56:05
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:07:48
User entered 'Oral (ORAL)'	Lalicia Roman (b) (4)	11 Sep 2020 14:56:05
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:07:52
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:56:05
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:07:53
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:56:05
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:07:54
User entered '1'	Lalicia Roman (b) (4)	11 Sep 2020 14:56:05
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:07:59
User entered 'Yes (Y)'	Lalicia Roman (b) (4)	11 Sep 2020 14:56:05
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:08:01
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:56:05
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:08:04
User entered 'No (N)'	Lalicia Roman (b) (4)	11 Sep 2020 14:56:05
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:56:05

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:56:05

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 14:56:05

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:08:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 04:55:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 04:55:42
Data point term sent to Coder Coding entries removed.	System Emily Carney (b) (4) (b) (4)	29 Oct 2020 15:40:37 29 Oct 2020 15:40:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:37:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:37:41
Data point term sent to Coder Data point term sent to Coder User entered 'fenofibrate'	System System Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 15:36:25 11 Sep 2020 14:57:16 11 Sep 2020 14:56:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:08:39
User entered 'No (N)'	Lalicia Roman (b) (4)	11 Sep 2020 14:56:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:14:23
User closed query 'Hypertriglyceride is not involved on the Medical History Form. "Hyper" not specified on the Conmed log in source. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 03:15:25
Query 'Hypertriglyceride is not involved on the Medical History Form. "Hyper" not specified on the Conmed log in source. ' answered with 'added' (Site from CRA).	Jennifer Nagg (b) (4)	04 Nov 2020 20:44:50
User opened query 'Hypertriglyceride is not involved on the Medical History Form. "Hyper" not specified on the Conmed log in source. ' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:15:14
User closed query 'Indication of Triglycerides(hyper/Hypo) is not included in the Medical History form. Please verify and reconcile in the Medical History form.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:15:14
Query 'Indication of Triglycerides(hyper/Hypo) is not included in the Medical History form. Please verify and reconcile in the Medical History form.' answered with 'updated' (Site from CRA).	Emily Carney (b) (4)	29 Oct 2020 15:40:08
User entered 'HyperTRIGLYCERIDES' reason for change: Data Entry Error	Emily Carney (b) (4)	29 Oct 2020 15:40:02
User opened query 'Indication of Triglycerides(hyper/Hypo) is not included in the Medical History form. Please verify and reconcile in the Medical History form.' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 03:31:32
User entered 'triglycerides'	Lalicia Roman (b) (4)	11 Sep 2020 14:56:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:08:49
User entered '48'	Lalicia Roman (b) (4)	11 Sep 2020 14:56:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:08:51
User entered 'mg (mg)'	Lalicia Roman (b) (4)	11 Sep 2020 14:56:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:08:54
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:56:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:08:56
User entered 'once daily (QD)'	Lalicia Roman (b) (4)	11 Sep 2020 14:56:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:08:57
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:56:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:08:59
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 15:35:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 15:35:44
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Dominic Kramer (b) (4)	11 Sep 2020 15:35:44
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 14:56:45
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:56:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:09:00
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:56:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:09:02
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:56:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:09:05
User entered '1'	Lalicia Roman (b) (4)	11 Sep 2020 14:56:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:09:07
User entered 'Yes (Y)'	Lalicia Roman (b) (4)	11 Sep 2020 14:56:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:09:08
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:56:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:09:10
User entered 'No (N)'	Lalicia Roman (b) (4)	11 Sep 2020 14:56:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:56:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:56:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 14:56:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:22:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 07:57:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 07:57:41
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 15:37:28
User entered 'VenlafaxineER'	Dominic Kramer (b) (4)	11 Sep 2020 15:36:46
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:22:32
User entered 'No (N)'	Dominic Kramer (b) (4)	11 Sep 2020 15:36:46
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:22:34
User closed query 'Anxiety is not listed in Medical History form. Please verify and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	01 Nov 2020 15:20:44
Query 'Anxiety is not listed in Medical History form. Please verify and reconcile. ' answered with 'anxiety listed on med hx' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 20:57:43
User opened query 'Anxiety is not listed in Medical History form. Please verify and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 03:22:46
User entered 'Anxiety'	Dominic Kramer (b) (4)	11 Sep 2020 15:36:46

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:22:39
User entered '150'	Dominic Kramer (b) (4)	11 Sep 2020 15:36:46
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:22:41
User entered 'mg (mg)'	Dominic Kramer (b) (4)	11 Sep 2020 15:36:46
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:23:10
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:36:46
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:22:45
User entered 'once daily (QD)'	Dominic Kramer (b) (4)	11 Sep 2020 15:36:46
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:22:47
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:36:46
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:22:50
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4)	11 Sep 2020 15:36:46
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:22:51
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:36:46
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:22:53
User entered 'UN UNK 2016'	Dominic Kramer (b) (4)	11 Sep 2020 15:36:46
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:22:56
User entered '0'	Dominic Kramer (b) (4)	11 Sep 2020 15:36:46
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:22:58
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	11 Sep 2020 15:36:46
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:23:03
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:36:46
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:16:08
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:19:30
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Lalicia Roman (b) (4)	13 Nov 2020 16:43:17
DataPoint Un-verified.	Lalicia Roman (b) (4)	13 Nov 2020 16:43:12
User entered 'No (N)' reason for change: Data Entry Error	Lalicia Roman (b) (4)	13 Nov 2020 16:43:12
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:21:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:23:04
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	11 Sep 2020 15:36:46

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:36:46

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:36:46

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 15:36:46

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:23:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 07:57:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 07:57:42
Data point term sent to Coder	System	11 Sep 2020 15:38:30
User entered 'VenlafaxineER'	Dominic Kramer (b) (4)	11 Sep 2020 15:37:40

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:23:55
User entered 'No (N)'	Dominic Kramer (b) (4)	11 Sep 2020 15:37:40
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:23:57
User entered 'Anxiety'	Dominic Kramer (b) (4)	11 Sep 2020 15:37:40
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:27:02
User entered '75'	Dominic Kramer (b) (4)	11 Sep 2020 15:37:40
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:23:59
User entered 'mg (mg)'	Dominic Kramer (b) (4)	11 Sep 2020 15:37:40
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:24:02
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:37:40
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:24:04
User entered 'once daily (QD)'	Dominic Kramer (b) (4)	11 Sep 2020 15:37:40
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:24:07
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:37:40
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:26:46
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4)	11 Sep 2020 15:37:40
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:26:47
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:37:40
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:26:50
User entered 'UN UNK 2016'	Dominic Kramer (b) (4)	11 Sep 2020 15:37:40
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:26:53
User entered '0'	Dominic Kramer (b) (4)	11 Sep 2020 15:37:40
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:26:55
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	11 Sep 2020 15:37:40
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:26:56
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:37:40
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:16:22
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:19:37
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Lalicia Roman (b) (4)	13 Nov 2020 16:43:34
DataPoint Un-verified.	Lalicia Roman (b) (4)	13 Nov 2020 16:43:28
User entered 'No (N)' reason for change: Data Entry Error	Lalicia Roman (b) (4)	13 Nov 2020 16:43:28
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:22:13
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:26:58
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	11 Sep 2020 15:37:40

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:37:40

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:37:40

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 15:37:40

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:57:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:57:38
Data point term sent to Coder Coding entries removed.	System Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:45:40 04 Nov 2020 20:45:13
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:27:39
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:39:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:39:35
Data point term sent to Coder User entered 'Atorvastatin'	System Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:38:31 11 Sep 2020 15:38:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:27:40
User entered 'No (N)'	Dominic Kramer (b) (4)	11 Sep 2020 15:38:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 13:49:45
User closed query 'Indication of Cholesterol(hyper/Hypo) is not included in the Medical History form. Please verify and reconcile in the Medical History form.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 13:49:44
Query 'Indication of Cholesterol(hyper/Hypo) is not included in the Medical History form. Please verify and reconcile in the Medical History form.' answered with 'added' (Site from CRA).	Jennifer Nagg (b) (4)	04 Nov 2020 20:45:18
User entered 'High CHOLESTEROL' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 20:45:13
User opened query 'Indication of Cholesterol(hyper/Hypo) is not included in the Medical History form. Please verify and reconcile in the Medical History form.' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 03:34:50
User entered 'Cholesterol'	Dominic Kramer (b) (4)	11 Sep 2020 15:38:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:29:27
User entered '40'	Dominic Kramer (b) (4)	11 Sep 2020 15:38:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:29:29
User entered 'mg (mg)'	Dominic Kramer (b) (4)	11 Sep 2020 15:38:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:29:31
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:38:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:33:52
User entered 'once daily (QD)'	Dominic Kramer (b) (4)	11 Sep 2020 15:38:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:29:35
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:38:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:29:37
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4)	11 Sep 2020 15:38:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:29:38
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:38:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:29:40
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:38:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:29:42
User entered '1'	Dominic Kramer (b) (4)	11 Sep 2020 15:38:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:29:43
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	11 Sep 2020 15:38:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:29:45
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:38:27
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:16:04
User closed query 'Please confirm if this medication was taken for a "solicited event" ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 03:15:50
Query 'Please confirm if this medication was taken for a "solicited event" ' answered with 'not taken for solicited event' (Site from CRA).	Jennifer Nagg (b) (4)	04 Nov 2020 20:45:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 20:45:25
User opened query 'Please confirm if this medication was taken for a "solicited event" ' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:36:38
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 17:29:50
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:29:47
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	11 Sep 2020 15:38:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:38:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:38:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 15:38:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4)	23 Nov 2020 11:26:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 16:18:37
Data point term sent to Coder	System	13 Nov 2020 16:44:41
Data point term sent to Coder	System	04 Nov 2020 20:52:54
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	04 Nov 2020 20:52:35
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'subject reported kenalog cream, uncertain of active ingredients' (Site from System).	Jennifer Nagg (b) (4)	04 Nov 2020 20:52:35
	(b) (4)	
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	14 Sep 2020 09:31:38
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 15:40:38
User entered 'Kenalog Ointment'	Dominic Kramer (b) (4)	11 Sep 2020 15:39:48
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:37:42
User entered 'No (N)'	Dominic Kramer (b) (4)	11 Sep 2020 15:39:48
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:18:43
User closed query 'Per DM CLR: Please specify the location and type of Rash. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:20:04
Query 'Per DM CLR: Please specify the location and type of Rash. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' answered with 'updated' (Site from DM).	Lalicia Roman (b) (4)	13 Nov 2020 16:44:40
DataPoint Un-verified.	(b) (4)	13 Nov 2020 16:44:33
User entered 'Generalized RASH' reason for change:	Lalicia Roman (b) (4)	13 Nov 2020 16:44:33
Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please specify the location and type of Rash. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:37:45
User entered 'Rash'	Dominic Kramer (b) (4)	11 Sep 2020 15:39:48

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Site response is noted. However, please update the Name of Medication field with KENALOG OINTMENT 30g. Also please update the specific dose and unit [e.g. 1 application (other), etc.] within the DOSE and UNIT fields. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 15:00:52
User closed query 'Per DM CLR: Please note, 30 g is a concentration/strength, rather than dosage. Please update the Con Med entry to list the specific dose and unit [e.g. 1 application (Other), etc.] within the DOSE and UNIT fields and provide the concentration/strength in the Name of Medication field. Update ConMed eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 15:00:52
Query 'Per DM CLR: Please note, 30 g is a concentration/strength, rather than dosage. Please update the Con Med entry to list the specific dose and unit [e.g. 1 application (Other), etc.] within the DOSE and UNIT fields and provide the concentration/strength in the Name of Medication field. Update ConMed eCRF as appropriate.' answered with 'Patient indicated the medication was 30g' (Site from DM).	Lalicia Roman (b) (4)	13 Nov 2020 16:45:09
User opened query 'Per DM CLR: Please note, 30 g is a concentration/strength, rather than dosage. Please update the Con Med entry to list the specific dose and unit [e.g. 1 application (Other), etc.] within the DOSE and UNIT fields and provide the concentration/strength in the Name of Medication field. Update ConMed eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 02:43:03
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:37:48
User entered '30'	Dominic Kramer (b) (4)	11 Sep 2020 15:39:48

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:37:53
User entered 'g (g)'	Dominic Kramer (b) (4)	11 Sep 2020 15:39:48
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:38
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:39:48
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:42
User entered 'as needed (PRN)'	Dominic Kramer (b) (4)	11 Sep 2020 15:39:48
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:47
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:39:48
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:51
User entered 'Topical (TOPICAL)'	Dominic Kramer (b) (4)	11 Sep 2020 15:39:48
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:39:05
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:39:48
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:39:48
User entered 'UN UNK 2017'	Dominic Kramer (b) (4)	11 Sep 2020 15:39:48
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:39:50
User entered '0'	Dominic Kramer (b) (4)	11 Sep 2020 15:39:48
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:39:52
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	11 Sep 2020 15:39:48
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:39:55
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:39:48
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:19:02
User closed query 'Please confirm response as "yes" to solicited event. thank you' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 03:16:21
Query 'Please confirm response as "yes" to solicited event. thank you' answered with 'updated' (Site from CRA).	Jennifer Nagg (b) (4)	04 Nov 2020 20:52:51
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	04 Nov 2020 20:52:43
	(b) (4)	
User opened query 'Please confirm response as "yes" to solicited event. thank you' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:49:39
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 17:40:08
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:40:07
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	11 Sep 2020 15:39:48
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 15:39:48

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 15:39:48

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 15:39:48

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:49:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 08:45:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	12 Sep 2020 08:45:44
Data point term sent to Coder	System	11 Sep 2020 15:41:43
User entered 'Levocetirizine'	Dominic Kramer (b) (4)	11 Sep 2020 15:40:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:49:58
User entered 'No (N)'	Dominic Kramer (b) (4)	11 Sep 2020 15:40:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:00
User entered 'Dust Allergies'	Dominic Kramer (b) (4)	11 Sep 2020 15:40:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:02
User entered '5'	Dominic Kramer (b) (4)	11 Sep 2020 15:40:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:03
User entered 'mg (mg)'	Dominic Kramer (b) (4)	11 Sep 2020 15:40:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:05
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:40:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:08
User entered 'once daily (QD)'	Dominic Kramer (b) (4)	11 Sep 2020 15:40:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:09
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:40:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:11
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4)	11 Sep 2020 15:40:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:13
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:40:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:14
User entered 'UN UNK 2015'	Dominic Kramer (b) (4)	11 Sep 2020 15:40:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:16
User entered '0'	Dominic Kramer (b) (4)	11 Sep 2020 15:40:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:17
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	11 Sep 2020 15:40:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:20
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:40:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:20:02
User closed query 'Please confirm response to solicited event . ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 03:16:33
Query 'Please confirm response to solicited event . ' answered with 'done' (Site from CRA).	Jennifer Nagg (b) (4)	04 Nov 2020 20:51:21
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	04 Nov 2020 20:51:15
	(b) (4)	
User opened query 'Please confirm response to solicited event . ' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:51:06
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:28
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:22
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	11 Sep 2020 15:40:45
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:40:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:40:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 15:40:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:42:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:42:36
Data point term sent to Coder	System	11 Sep 2020 15:41:44
User entered 'Vitamin D3'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:41:41

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:20:42
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:22:57
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'done' (Site from DM).	Jennifer Nagg (b) (4)	04 Nov 2020 20:49:40
DataPoint Un-verified.	(b) (4)	04 Nov 2020 20:49:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	04 Nov 2020 20:49:35
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 02:31:50
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:28
User entered 'No (N)'	Dominic Kramer (b) (4)	11 Sep 2020 15:41:41

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:20:49
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 16:20:44
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:45
User entered 'Supplement'	Dominic Kramer (b) (4)	11 Sep 2020 15:41:41
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:20:51
DataPoint Un-verified.	Jennifer Nagg (b) (4)	04 Nov 2020 20:50:53
	(b) (4)	
User entered '2000' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	04 Nov 2020 20:50:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:54
User entered '50'	Dominic Kramer (b) (4)	11 Sep 2020 15:41:41
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:20:55
DataPoint Un-verified.	Jennifer Nagg (b) (4)	04 Nov 2020 20:50:53
	(b) (4)	
User entered 'IU (IU)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	04 Nov 2020 20:50:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:59
User entered 'Other (OTHER)'	Dominic Kramer (b) (4)	11 Sep 2020 15:41:41
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:20:59
User closed query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 11:35:33
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' answered with 'done' (Site from DM).	Jennifer Nagg (b) (4)	04 Nov 2020 20:50:59
User entered empty; reason for change Data Entry Error	Jennifer Nagg (b) (4)	04 Nov 2020 20:50:53
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:30:36
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "mg" from the drop down list. Please update accordingly. Else Clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:30:30

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "mg" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM). User entered 'Mcg'	(b) (4), (b) (6) (b) (4)	27 Oct 2020 14:15:06
	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:41:41

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:55:05
User entered 'once daily (QD)'	Dominic Kramer (b) (4)	11 Sep 2020 15:41:41
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:55:07
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:41:41
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:55:08
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4)	11 Sep 2020 15:41:41
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:55:10
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:41:41
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:55:12
User entered 'UN UNK 2015'	Dominic Kramer (b) (4)	11 Sep 2020 15:41:41
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:55:13
User entered '0'	Dominic Kramer (b) (4)	11 Sep 2020 15:41:41
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:55:14
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	11 Sep 2020 15:41:41
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:55:16
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:41:41
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:55:19
User entered 'No (N)'	Dominic Kramer (b) (4)	11 Sep 2020 15:41:41
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:41:41

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:41:41

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 15:41:41

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:31:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:11:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:11:48
Data point term sent to Coder	System	04 Nov 2020 21:00:19
User entered 'heparin'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 21:00:16

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:31:47
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	04 Nov 2020 21:00:16
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:31:51
User entered 'clot prevention'	Jennifer Nagg (b) (4)	04 Nov 2020 21:00:16
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:31:53
User entered '5000'	Jennifer Nagg (b) (4)	04 Nov 2020 21:00:16
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:31:57
User entered 'Other (OTHER)'	Jennifer Nagg (b) (4)	04 Nov 2020 21:00:16
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:36:56
User entered 'units'	Jennifer Nagg (b) (4)	04 Nov 2020 21:00:16
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:16
User entered 'three times daily (TID)'	Jennifer Nagg (b) (4)	04 Nov 2020 21:00:16
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:20
User entered empty.	Jennifer Nagg (b) (4)	04 Nov 2020 21:00:16
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:23
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jennifer Nagg (b) (4)	04 Nov 2020 21:00:16
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:36
User entered empty.	Jennifer Nagg (b) (4)	04 Nov 2020 21:00:16
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:33:52
User entered '29 Oct 2020'	Jennifer Nagg (b) (4)	04 Nov 2020 21:00:16
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:34:28
User entered '0'	Jennifer Nagg (b) (4)	04 Nov 2020 21:00:16
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:34:26
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	04 Nov 2020 21:00:16
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:34:29
User entered empty.	Jennifer Nagg (b) (4)	04 Nov 2020 21:00:16
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:34:31
User entered 'No (N)'	Jennifer Nagg (b) (4)	04 Nov 2020 21:00:16
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	04 Nov 2020 21:00:16

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 21:00:16

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 21:00:16

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:06
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)	12 Nov 2020 16:01:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	12 Nov 2020 16:01:31
Data point term sent to Coder	System	12 Nov 2020 16:00:42
User entered 'Flu vaccine'	Emily Carney (b) (4)	12 Nov 2020 16:00:19
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:08
User entered 'Yes (Y)'	Emily Carney (b) (4)	12 Nov 2020 16:00:19
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:10
User entered 'Prevent influenza infection'	Emily Carney (b) (4)	12 Nov 2020 16:00:19
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:11
User entered 'Unk'	Emily Carney (b) (4)	12 Nov 2020 16:00:19
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:13
User entered 'mL (mL)'	Emily Carney (b) (4)	12 Nov 2020 16:00:19
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:16
User entered empty.	Emily Carney (b) (4)	12 Nov 2020 16:00:19
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:18
User entered 'once (ONCE)'	Emily Carney (b) (4)	12 Nov 2020 16:00:19
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:19
User entered empty.	Emily Carney (b) (4)	12 Nov 2020 16:00:19
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:21
User entered 'Intramuscular (INTRAMUSCULAR)'	Emily Carney (b) (4)	12 Nov 2020 16:00:19
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:23
User entered empty.	Emily Carney (b) (4)	12 Nov 2020 16:00:19
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:25
User entered '6 Nov 2020'	Emily Carney (b) (4)	12 Nov 2020 16:00:19
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:28
User entered '0'	Emily Carney (b) (4)	12 Nov 2020 16:00:19
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:30
User entered 'No (N)'	Emily Carney (b) (4)	12 Nov 2020 16:00:19
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:31
User entered '6 Nov 2020'	Emily Carney (b) (4)	12 Nov 2020 16:00:19
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:33
User entered 'No (N)'	Emily Carney (b) (4)	12 Nov 2020 16:00:19
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 16:00:19

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 16:00:19

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 17:01:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 16:00:19

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 17:01:20

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:01:11
User entered 'Yes (Y)'	Emily Carney (b) (4)	12 Nov 2020 16:00:53
	(b) (4)	

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 17:01:20

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:03:50
User entered '30 Oct 2020'	Emily Carney (b) (4)	12 Nov 2020 16:02:34
	(b) (4)	

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 17:01:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:03:50
User entered 'paraesophageal hernia repair'	Emily Carney (b) (4)	12 Nov 2020 16:02:34
	(b) (4)	

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 17:01:20

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:03:50
User entered 'Medical History (MH)'	Emily Carney (b) (4)	12 Nov 2020 16:02:34
	(b) (4)	

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 17:01:20

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:03:50
User entered empty.	Emily Carney (b) (4)	12 Nov 2020 16:02:34
	(b) (4)	

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'USA-US098-2020-MRNA-1273-P301000001'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Judith'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Martin'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered '3420 Fifth Ave'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Pittsburgh'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'PA'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered '15213'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:51:07
User entered 'US'	System	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Nov 2020 14:55:04
User entered '3'	System	12 Nov 2020 12:53:22
User entered '2'	System	11 Nov 2020 15:51:19
User entered '1'	System	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'USA-US098-2020-MRNA-1273-P301000001'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Judith'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Martin'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered '3420 Fifth Ave'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Pittsburgh'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'PA'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered '15213'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:51:07
User entered 'US'	System	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Nov 2020 14:55:04
User entered '3'	System	12 Nov 2020 12:53:22
User entered '2'	System	11 Nov 2020 15:51:19
User entered '1'	System	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 17:01:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
User entered '03/Nov/2020 17:24'	System	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 17:01:20

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)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:51:07
User entered '1'	(b) (4), (b) (6)	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'USA-US098-2020-MRNA-1273-P301000001'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Judith'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Martin'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered '3420 Fifth Ave'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Pittsburgh'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'PA'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered '15213'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:51:07
User entered 'US'	System	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Nov 2020 14:55:04
User entered '3'	System	12 Nov 2020 12:53:22
User entered '2'	System	11 Nov 2020 15:51:19
User entered '1'	System	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 17:01:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
User entered '11/Nov/2020 15:51'	System	11 Nov 2020 15:51:19

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 17:01:20

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)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:53:13
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 15:51:19

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'USA-US098-2020-MRNA-1273-P301000001'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Judith'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Martin'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered '3420 Fifth Ave'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Pittsburgh'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'PA'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered '15213'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:51:07
User entered 'US'	System	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Nov 2020 14:55:04
User entered '3'	System	12 Nov 2020 12:53:22
User entered '2'	System	11 Nov 2020 15:51:19
User entered '1'	System	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 17:01:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
User entered '12/Nov/2020 07:53'	System	12 Nov 2020 12:53:22

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 17:01:20

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)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:54:55
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 12:53:22

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'USA-US098-2020-MRNA-1273-P301000001'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Judith'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Martin'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered '3420 Fifth Ave'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Pittsburgh'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'PA'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered '15213'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:51:07
User entered 'US'	System	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 17:01:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Nov 2020 14:55:04
User entered '3'	System	12 Nov 2020 12:53:22
User entered '2'	System	11 Nov 2020 15:51:19
User entered '1'	System	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 17:01:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:47:54
User entered '16/Nov/2020 09:55'	System	16 Nov 2020 14:55:04

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 17:01:20

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)	18 Nov 2020 15:47:54
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 14:55:04