

US3372060 (Prod: Palm Beach Research Center)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:02:00

All time stamps listed in this document are displayed in GMT

US3372060

Form: Participant Creation

Generated On: 26 Nov 2020 11:02:00

[Participant ID](#)

US3372060

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

US3372060

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3372060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:00

Date of Birth (MMM yyyy)	(b) (6) 1960
Age	60
Age Units	YEARS
Age (Derived)	60
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

US3372060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:00

Date of Informed Consent (<i>dd MMM yyyy</i>)	07 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☒
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

US3372060

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:02:00

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3372060

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:02:00

Were any significant conditions reported?

Yes ☒

No ☐

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:00

Condition	TORN MENISCUS RIGHT KNEE
Start date (dd MMM yyyy)	UN APR 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN APR 1996
Stop date completely unknown	False
Start Month and Year (derived)	APR 1996
Start Year (derived)	1996
Stop Month and Year (derived)	APR 1996
Stop Year (derived)	1996

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:00

Condition	ARTHROPLASTY RIGHT KNEE
Start date (dd MMM yyyy)	UN APR 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN APR 1996
Stop date completely unknown	False
Start Month and Year (derived)	APR 1996
Start Year (derived)	1996
Stop Month and Year (derived)	APR 1996
Stop Year (derived)	1996

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:00

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN SEP 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN SEP 2014
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2014
Start Year (derived)	2014
Stop Month and Year (derived)	SEP 2014
Stop Year (derived)	2014

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:00

Condition	CORONARY ARTERY ANGIOPLASTY
Start date (dd MMM yyyy)	UN SEP 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN SEP 2014
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2014
Start Year (derived)	2014
Stop Month and Year (derived)	SEP 2014
Stop Year (derived)	2014

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:00

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	07 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:30 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 10:30
Height (<i>xxx.x</i>)	169.9 cm
Weight (<i>xxx.x</i>)	82 kg
BMI (<i>xxx.x</i>)	28.40711 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372060

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3372060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:00

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 101380

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 ☒

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:00

Height	ND - Not Done
Weight	ND - Not Done

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 10:30
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	12:52 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 12:52
Temperature (xxx.x)	36.7 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3372060

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

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)	7 AUG 2020
What was the treatment time? (00:00-23:59)	12:13 (24 HR)
Treatment Date and Time (derived)	7 AUG 2020 12:13
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

US3372060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:00

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 AUG 2020

Collection time (00:00-23:59)

11:19 (24 HR)

Collection date and time (derived)

7 AUG 2020 11:19

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:02:00

Collection date (dd MMM yyyy)			7 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:17	7 AUG 2020 11:17
Nasopharyngeal Swab 2	No		

US3372060

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 12:51

PC Open Date & Time

07 AUG 2020 12:33

PC Close Date & Time

07 AUG 2020 15:03

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

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

97.2 °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	07 AUG 2020 21:24
PC Open Date & Time	07 AUG 2020 15:58
PC Close Date & Time	08 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:00

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

08 AUG 2020 18:41

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 19:20

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

10 AUG 2020 22:28

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 20:45

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:00

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

98.6 °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

12 AUG 2020 19:21

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:00

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

98.9 °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

13 AUG 2020 21:12

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

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

07 AUG 2020 12:53

PC Open Date & Time

07 AUG 2020 12:33

PC Close Date & Time

07 AUG 2020 15:03

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

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

07 AUG 2020 21:25

PC Open Date & Time

07 AUG 2020 15:58

PC Close Date & Time

08 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:00

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

08 AUG 2020 18:41

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:00

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

09 AUG 2020 19:21

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:00

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

10 AUG 2020 22:28

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:00

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

11 AUG 2020 20:45

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:00

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

12 AUG 2020 19:21

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:00

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

13 AUG 2020 21:12

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 12:53
PC Open Date & Time	07 AUG 2020 12:33
PC Close Date & Time	07 AUG 2020 15:03

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 21:26
PC Open Date & Time	07 AUG 2020 15:58
PC Close Date & Time	08 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

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 ☒

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

Yes ☐	
PC Time stamp	08 AUG 2020 18:42
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

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 ☒

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

Yes ☐	
PC Time stamp	09 AUG 2020 19:21
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

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 ☒

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

Yes ☐	
PC Time stamp	10 AUG 2020 22:28
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

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 ☒

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

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 ☒

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

Yes ☐	
PC Time stamp	12 AUG 2020 19:22
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

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 ☒

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

Yes ☐	
PC Time stamp	13 AUG 2020 21:12
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3372060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	10:34 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 10:34
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	12:11 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 12:11
Temperature (xxx.x)	36.7 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3372060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

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)	10 SEP 2020
What was the treatment time? (00:00-23:59)	11:34 (24 HR)
Treatment Date and Time (derived)	10 SEP 2020 11:34
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

US3372060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:00

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

10 SEP 2020

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

10:58 (24 HR)

Collection date and time (derived)

10 SEP 2020 10:58

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:02:00

Collection date (<i>dd MMM yyyy</i>)			10 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	10:57	10 SEP 2020 10:57
Nasopharyngeal Swab 2	No		

US3372060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

10 SEP 2020 12:10

PC Open Date & Time

10 SEP 2020 11:54

PC Close Date & Time

10 SEP 2020 14:24

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °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	10 SEP 2020 19:48
PC Open Date & Time	10 SEP 2020 15:19
PC Close Date & Time	11 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:00

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

98.8 °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

11 SEP 2020 18:32

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:00

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

98.3 °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

12 SEP 2020 22:15

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

13 SEP 2020 22:40

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:00

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

98.5 °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 SEP 2020 09:38

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:00

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

94.3 °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

15 SEP 2020 21:29

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:00

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

99.3 °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 SEP 2020 20:38

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

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

10 SEP 2020 12:11

PC Open Date & Time

10 SEP 2020 11:54

PC Close Date & Time

10 SEP 2020 14:24

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

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

10 SEP 2020 19:48

PC Open Date & Time

10 SEP 2020 15:19

PC Close Date & Time

11 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:00

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

11 SEP 2020 18:32

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:00

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

12 SEP 2020 22:15

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:00

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

13 SEP 2020 22:41

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:00

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 09:38

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:00

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

15 SEP 2020 21:30

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:00

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

16 SEP 2020 20:38

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 12:11
PC Open Date & Time	10 SEP 2020 11:54
PC Close Date & Time	10 SEP 2020 14:24

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 19:49
PC Open Date & Time	10 SEP 2020 15:19
PC Close Date & Time	11 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

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 ☒

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

Yes ☐	
PC Time stamp	11 SEP 2020 18:33
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

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 ☒

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

Yes ☐	
PC Time stamp	12 SEP 2020 22:16
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

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 ☒

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

Yes ☐	
PC Time stamp	13 SEP 2020 22:41
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

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 ☒

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

Yes ☐	
PC Time stamp	15 SEP 2020 09:41
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

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 ☒

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

Yes ☐	
PC Time stamp	15 SEP 2020 21:30
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

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 ☒

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

Yes ☐	
PC Time stamp	16 SEP 2020 20:39
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3372060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	02 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 OCT 2020

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

US3372060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:00

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	02 OCT 2020
Collection time (<i>00:00-23:59</i>)	10:16 (24 HR)
Collection date and time (derived)	02 OCT 2020 10:16

US3372060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

07 OCT 2020 15:20:49

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 OCT 2020 16:14:52

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 OCT 2020 09:19:16

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 NOV 2020 19:58:53

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

15 NOV 2020 22:17:18

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2020 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2020 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2020 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2020 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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°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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 17:57:49
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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

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

US3372060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

Was Contact Attempted?

Yes ☒

No ☐

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

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372060

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3372060

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:02:00

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3372060

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:02:00

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

AEID	USA-US056-2020-MRNA-1273-P30 1000004
Adverse event	RIGHT HIP TRAUMA
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)	14 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	16 AUG 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)	14 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	16 AUG 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	341 of 2010

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	AFTER A BICYCLE-MOTOR VEHICLE ACCIDENT WENT TO DELRAY MEDICAL CENTER FROM 08/14/2020 TO 08/16/2020 WITH RIGHT HIP AND RIGHT KNEE TRAUMA
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	0
v6.020 DTW (1102)	342 of 2010

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

AEID	USA-US056-2020-MRNA-1273-P30 1000004
Adverse event	RIGHT KNEE TRAUMA
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)	14 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	04 SEP 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)	14 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	16 AUG 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	343 of 2010

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☐ Related ☐ Not Applicable ☒
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	AFTER A BICYCLE-MOTOR VEHICLE ACCIDENT WENT TO DELRAY MEDICAL CENTER FROM 08/14/2020 TO 08/16/2020 WITH RIGHT HIP AND RIGHT KNEE TRAUMA
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	0
v6.020 DTW (1102)	344 of 2010

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

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

v6.020 DTW (1102)

345 of 2010

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:02:00

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

Yes ☒

No ☐

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

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

	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	☒

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

Name of Medication	OXYCONTIN
Prophylaxis	Yes ☐ No ☒
Indication	BILATERAL KNEE PAIN
Dose per administration	15
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 ☐

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

	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	☒

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ☒ No ☐
Indication	INFLUENZA PROPHYLAXIS/PREVENTION
Dose per administration	0.25
Dose unit	mg ☐ ug ☐ mL ☒ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

	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 SEP 2019	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		UN SEP 2019
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	☐

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

Name of Medication	OXYCONTIN
Prophylaxis	Yes ☐ No ☒
Indication	LOWER BACK PAIN
Dose per administration	15
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 ☐

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

Name of Medication	DOXYCYCLINE
Prophylaxis	Yes ☒ No ☐
Indication	RIGHT KNEE TRAUMA LACERATION INFECTION PREVENTION
Dose per administration	100
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

	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)	16 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	26 AUG 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

Name of Medication	PANCRELIPASE
Prophylaxis	Yes ☐ No ☒
Indication	PANCREATIC ENZYME REPLACEMENT
Dose per administration	36000
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 ☐

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

	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)	15 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy) 16 AUG 2020		
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

Name of Medication PERCOCET 5/325

Prophylaxis Yes ☐
No ☒

Indication RIGHT KNEE PAIN

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 ☐

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

	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)	14 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		14 AUG 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	☐

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

Name of Medication	CEFAZOLIN
Prophylaxis	Yes ☐ No ☒
Indication	RIGHT KNEE LACERATION
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 ☐

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

	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)	14 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		14 AUG 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	☐

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

Name of Medication	IOPAMIDOL
Prophylaxis	Yes ☐ No ☒
Indication	RADIOPAQUE CONTRAST AGENT
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 ☐

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

	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)	14 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		14 AUG 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 ☐	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

Name of Medication	ADACEL (TDAP)
Prophylaxis	Yes ☐ No ☒
Indication	TETANUS PROPHYLAXIS/PREVENTION
Dose per administration	0.5
Dose unit	mg ☐ ug ☐ mL ☒ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

	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)	14 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		14 AUG 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 ☐	

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:02:00

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:02:00

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
14 AUG 2020	CAT SCAN OF THE ABDOMEN	Adverse Event	
14 AUG 2020	CAT SCAN OF THE CERVICAL SPINE	Adverse Event	
14 AUG 2020	X-RAY OF RIGHT KNEE	Adverse Event	

US3372060

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:02:00

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

US3372060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:02:00

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 ☐

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

SAEID	USA-US056-2020-MRNA-1273-P301000004
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	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:02:00

SAEID	USA-US056-2020-MRNA-1273-P301000004
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	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	05/OCT/2020 08:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:02:00

SAEID	USA-US056-2020-MRNA-1273-P301000004
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	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/OCT/2020 14:03
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

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:02:00

SAEID	USA-US056-2020-MRNA-1273-P301000004
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	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	09/NOV/2020 20:53
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

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:02:00

SAEID	USA-US056-2020-MRNA-1273-P301000004
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	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/NOV/2020 17:55
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

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:02:00

SAEID	USA-US056-2020-MRNA-1273-P301000004
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	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/NOV/2020 18:04
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

US3372060 (Prod: Palm Beach Research Center)

US3372060

Form: Participant Creation

Generated On: 26 Nov 2020 11:02:00

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3372060'	RWS_ENDPOINT ENDPOINT (b) (4) 	07 Aug 2020 13:39:55

US3372060

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 14:34:38

US3372060

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 13:39:56

US3372060

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Aug 2020 14:34:38

US3372060

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	07 Aug 2020 14:34:38

US3372060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:00

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1960'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 13:39:57

US3372060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:00

[Age](#)

Audit	User	Time (GMT)
User entered '60'	(b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:00

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:00

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '60'	System	07 Aug 2020 14:35:17

US3372060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:00

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	(b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:00

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:00

White

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:00

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:00

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:00

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:00

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:00

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:00

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:00

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:00

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 14:34:53

US3372060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '07 Aug 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	10 Nov 2020 17:39:55
User entered '7 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 14:35:17

US3372060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	07 Aug 2020 14:35:17

US3372060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '2020'	System	07 Aug 2020 14:35:17

US3372060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:00

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	07 Aug 2020 14:35:17

US3372060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 14:35:17

US3372060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:35:17

US3372060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:00

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:35:17

US3372060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:00

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 14:35:17

US3372060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:00

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 13:39:56

US3372060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:00

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 14:35:29

US3372060

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 14:35:29

US3372060

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:02:00

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:25:00

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear of knee - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:29:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:29:14
Data point term sent to Coder	System	11 Aug 2020 20:28:15
User entered 'torn meniscus right knee'	Peter Jacob (b) (4)	11 Aug 2020 20:27:41
	(b) (4)	

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'un Apr 1996'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'un Apr 1996'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Apr 1996'	System	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '1996'	System	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Apr 1996'	System	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '1996'	System	11 Aug 2020 20:27:41

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Arthroplasty of knee - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:04:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:04:16
Data point term sent to Coder	System	11 Aug 2020 20:28:16
User entered 'arthroplasty right knee'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'un Apr 1996'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'un Apr 1996'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Apr 1996'	System	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '1996'	System	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Apr 1996'	System	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '1996'	System	11 Aug 2020 20:28:01

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:30:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:30:15
Data point term sent to Coder	System	11 Aug 2020 20:29:19
User entered 'coronary artery disease'	Peter Jacob (b) (4)	11 Aug 2020 20:28:25
	(b) (4)	

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'un Sep 2014'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'un Sep 2014'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Sep 2014'	System	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '2014'	System	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Sep 2014'	System	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '2014'	System	11 Aug 2020 20:28:25

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary angioplasty, LLT: Coronary angioplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 21:23:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 21:23:16
Data point term sent to Coder	System	11 Aug 2020 20:30:22
User entered 'coronary artery angioplasty'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'UN Sep 2014' reason for change: Data Entry Error	Peter Jacob (b) (4)	05 Oct 2020 20:11:49
User entered 'un UNK 2014'	Peter Jacob (b) (4)	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, the condition on MH# 3 has a stop date of UN SEP 2014. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:46:53
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, the condition on MH# 3 has a stop date of UN SEP 2014. Please correct dates or provide explanation for the Med History duration. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4)	05 Oct 2020 20:11:54
User entered 'UN Sep 2014' reason for change: Data Entry Error	Peter Jacob (b) (4)	05 Oct 2020 20:11:49
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, the condition on MH# 3 has a stop date of UN SEP 2014. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 20:37:54
User entered 'un UNK 2014'	Peter Jacob (b) (4)	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Sep 2014'	System	05 Oct 2020 20:11:49
User entered 'Jan 2014'	System	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '2014'	System	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Sep 2014'	System	05 Oct 2020 20:11:49
User entered 'Jan 2014'	System	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '2014'	System	11 Aug 2020 20:29:26

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Head injury, LLT: Head injury - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 12:29:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 12:29:21
Data point term sent to Coder	System	11 Aug 2020 20:31:26
User entered 'head trauma'	Peter Jacob (b) (4)	11 Aug 2020 20:30:48
	(b) (4)	

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'un Sep 2018'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'un Sep 2018'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Sep 2018'	System	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '2018'	System	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Sep 2018'	System	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '2018'	System	11 Aug 2020 20:30:48

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 16:56:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 16:56:21
Data point term sent to Coder	System	06 Oct 2020 16:54:56
User entered 'insomnia'	Peter Jacob (b) (4)	06 Oct 2020 16:54:17
	(b) (4)	

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '2017'	System	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:54:17

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 16:58:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 16:58:18
Data point term sent to Coder	System	06 Oct 2020 16:56:59
User entered 'bilateral knee pain'	Peter Jacob (b) (4)	06 Oct 2020 16:56:05
	(b) (4)	

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '2018'	System	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:56:05

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:58:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:58:17
Data point term sent to Coder	System	06 Oct 2020 16:56:59
User entered 'chronic lower back pain'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '2018'	System	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:56:17

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Aug 2020'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '10:30'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '07 Aug 2020 10:30'	System	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '169.9' cm	Peter Jacob (b) (4)	11 Aug 2020 21:31:25
DataPoint set to visible.	(b) (4) System	07 Aug 2020 14:35:29

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '82' kg	Peter Jacob (b) (4)	11 Aug 2020 21:31:25
DataPoint set to visible.	(b) (4) System	07 Aug 2020 14:35:29

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '28.40711'	System	16 Sep 2020 23:46:56
User entered '28.4'	System	11 Aug 2020 21:31:25
DataPoint set to visible.	System	07 Aug 2020 14:35:29

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	11 Aug 2020 21:31:25
DataPoint set to visible.	System	07 Aug 2020 14:35:29

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:17:12
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4)	29 Sep 2020 15:39:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:38:33
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:36:31
User entered '36.8' C	Peter Jacob (b) (4)	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 15:38:33
User entered 'Oral (Oral)'	Peter Jacob (b) (4)	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 15:38:33
User entered '74'	Peter Jacob (b) (4)	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 15:38:33
User entered '16'	Peter Jacob (b) (4)	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 15:38:33
User entered '116'	Peter Jacob (b) (4)	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 15:38:33
User entered '83'	Peter Jacob (b) (4)	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 21:31:25

US3372060

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:34:24

US3372060

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 22:16:43
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		10 Sep 2020 15:42:51
User entered '07 Aug 2020'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:34:24

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:00

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 15:53:28

US3372060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:34:48

US3372060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '07 Aug 2020'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:34:48

US3372060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:34:48

US3372060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	11 Aug 2020 21:34:48

US3372060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	07 Aug 2020 15:45:05

US3372060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:00

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:47:32
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:47:32
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 15:45:05
User entered '101380' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 15:45:05

US3372060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 15:45:05

US3372060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:54:54

US3372060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
Comment added 'dcf submitted'.	Mary Sergalis (b) (4)	19 Nov 2020 20:30:56
Comment added 'DCF submitted to endpoint to correct stratification'.	Mary Sergalis (b) (4)	10 Nov 2020 18:31:12
Comment added 'dcf SUBMITTED FOR CORRECTION ON 07-NOV-2020'.	Mary Sergalis (b) (4)	07 Nov 2020 15:59:19
Comment added 'Unable to update to correct at risk status'.	Mary Sergalis (b) (4)	22 Oct 2020 13:32:25
User opened query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	07 Aug 2020 15:54:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 15:54:54

US3372060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:54:54

US3372060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:00

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:54:54

US3372060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:00

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:54:54

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:00

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:17:09
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4)	29 Sep 2020 14:51:45
answered with 'data updated' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 14:51:26
	(b) (4)	
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:36:23
User entered '169.9' cm	Peter Jacob (b) (4)	11 Aug 2020 21:39:45
	(b) (4)	

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:00

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 14:51:26
User entered '82' kg	Peter Jacob (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:00

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:17:09
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4)	29 Sep 2020 14:51:45
answered with 'data updated' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 14:51:26
	(b) (4)	
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:36:23
User entered '169.9' cm	Peter Jacob (b) (4)	11 Aug 2020 21:39:45
	(b) (4)	

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:00

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 14:51:26
User entered '82' kg	Peter Jacob (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Aug 2020'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '10:30'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '07 Aug 2020 10:30'	System	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '16'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '116'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '83'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:00

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:17:09
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4)	29 Sep 2020 14:51:45
answered with 'data updated' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 14:51:26
	(b) (4)	
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:36:23
User entered '169.9' cm	Peter Jacob (b) (4)	11 Aug 2020 21:39:45
	(b) (4)	

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:00

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 14:51:26
User entered '82' kg	Peter Jacob (b) (4)	11 Aug 2020 21:39:45

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Aug 2020'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 05:09:13
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol post-dose vital signs must be collected at least 30 minutes after dose time' (Site from System).	Peter Jacob (b) (4)	11 Aug 2020 21:43:02
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	11 Aug 2020 21:41:41
User entered '12:52'	Peter Jacob (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:52'	System	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '69'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '16'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '121'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '85'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 21:41:41

US3372060

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:00

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:43:08

US3372060

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:00

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Aug 2020'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 21:43:08

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '7 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '12:13'	(b) (4), (b) (6)	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '7 Aug 2020 12:13'	System	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 16:31:32

US3372060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 18:53:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 18:53:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:53:27
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 16:33:11
User entered empty.	(b) (4), (b) (6) (b) (4)	07 Aug 2020 16:33:11

US3372060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 16:33:11

US3372060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:00

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:19'	(b) (4), (b) (6)	07 Aug 2020 16:33:11

US3372060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '7 Aug 2020 11:19'	System	07 Aug 2020 16:33:11

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:02:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 16:32:48

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:02:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	07 Aug 2020 16:32:48

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:02:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 16:32:48

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:02:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:17'	(b) (4), (b) (6)	07 Aug 2020 16:32:48

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '7 Aug 2020 11:17'	System	07 Aug 2020 16:32:48

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:02:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	07 Aug 2020 16:32:48

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:02:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 18:44:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 18:44:12
User entered 'No (N)' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:44:12
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 16:32:48
User entered empty.	(b) (4), (b) (6) (b) (4)	07 Aug 2020 16:32:48

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:02:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 16:32:48

US3372060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 16:32:48

US3372060

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 22:16:39

US3372060

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:16:39

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:49:34', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '606058d1-8220-4c78-aa48-f8d1b7377595'	System	07 Aug 2020 16:51:18
User entered 'Yes (Y)'	System	07 Aug 2020 16:51:18

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:50:45', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '606058d1-8220-4c78-aa48-f8d1b7377595'	System	07 Aug 2020 16:51:18
User entered '98.2'	System	07 Aug 2020 16:51:18

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:51:05', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '606058d1-8220-4c78-aa48-f8d1b7377595'	System	07 Aug 2020 16:51:18
User entered 'No (N)'	System	07 Aug 2020 16:51:18

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:51:14', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '606058d1-8220-4c78-aa48-f8d1b7377595'	System	07 Aug 2020 16:51:18
User entered '07 Aug 2020 12:51'	System	07 Aug 2020 16:51:18

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:33'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 15:03'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:24:20', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5db7a8da-43ac-4ace-88b5-fbd7e0b14ae4'	System	08 Aug 2020 01:24:50
User entered 'Yes (Y)'	System	08 Aug 2020 01:24:50

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:24:29', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5db7a8da-43ac-4ace-88b5-fbd7e0b14ae4'	System	08 Aug 2020 01:24:50
User entered '97.2'	System	08 Aug 2020 01:24:50

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:24:36', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5db7a8da-43ac-4ace-88b5-fbd7e0b14ae4'	System	08 Aug 2020 01:24:50
User entered 'No (N)'	System	08 Aug 2020 01:24:50

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:24:48', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5db7a8da-43ac-4ace-88b5-fbd7e0b14ae4'	System	08 Aug 2020 01:24:50
User entered '07 Aug 2020 21:24'	System	08 Aug 2020 01:24:50

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 15:58'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 2'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:10', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7dadebca-6510-4667-8d23-75c8a4bfd39b'	System	08 Aug 2020 22:41:25
User entered 'Yes (Y)'	System	08 Aug 2020 22:41:25

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:16', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7dadebca-6510-4667-8d23-75c8a4bfd39b'	System	08 Aug 2020 22:41:25
User entered '98.2'	System	08 Aug 2020 22:41:25

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:20', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7dadebca-6510-4667-8d23-75c8a4bfd39b'	System	08 Aug 2020 22:41:25
User entered 'No (N)'	System	08 Aug 2020 22:41:25

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:23', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7dadebca-6510-4667-8d23-75c8a4bfd39b'	System	08 Aug 2020 22:41:25
User entered '08 Aug 2020 18:41'	System	08 Aug 2020 22:41:25

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 3'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:20:34', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '92167933-829e-4a82-a0c4-c1e1de9993c3'	System	09 Aug 2020 23:20:52
User entered 'Yes (Y)'	System	09 Aug 2020 23:20:52

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:20:42', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '92167933-829e-4a82-a0c4-c1e1de9993c3'	System	09 Aug 2020 23:20:52
User entered '98.7'	System	09 Aug 2020 23:20:52

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:20:46', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '92167933-829e-4a82-a0c4-c1e1de9993c3'	System	09 Aug 2020 23:20:52
User entered 'No (N)'	System	09 Aug 2020 23:20:52

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:20:49', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '92167933-829e-4a82-a0c4-c1e1de9993c3'	System	09 Aug 2020 23:20:52
User entered '09 Aug 2020 19:20'	System	09 Aug 2020 23:20:52

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 4'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:27:47', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'c87748ec-06f6-4055-bdda-96094bfe3fc4'	System	11 Aug 2020 02:28:07
User entered 'Yes (Y)'	System	11 Aug 2020 02:28:07

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:27:53', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'c87748ec-06f6-4055-bdda-96094bfe3fc4'	System	11 Aug 2020 02:28:07
User entered '97.3'	System	11 Aug 2020 02:28:07

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:27:59', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'c87748ec-06f6-4055-bdda-96094bfe3fc4'	System	11 Aug 2020 02:28:07
User entered 'No (N)'	System	11 Aug 2020 02:28:07

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:02', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'c87748ec-06f6-4055-bdda-96094bfe3fc4'	System	11 Aug 2020 02:28:07
User entered '10 Aug 2020 22:28'	System	11 Aug 2020 02:28:07

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 5'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '622691f9-b859-4983-aa38-9c34dfc2725f'	System	12 Aug 2020 00:45:20
User entered 'Yes (Y)'	System	12 Aug 2020 00:45:20

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:09', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '622691f9-b859-4983-aa38-9c34dfc2725f'	System	12 Aug 2020 00:45:20
User entered '98.1'	System	12 Aug 2020 00:45:20

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '622691f9-b859-4983-aa38-9c34dfc2725f'	System	12 Aug 2020 00:45:20
User entered 'No (N)'	System	12 Aug 2020 00:45:20

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:17', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '622691f9-b859-4983-aa38-9c34dfc2725f'	System	12 Aug 2020 00:45:20
User entered '11 Aug 2020 20:45'	System	12 Aug 2020 00:45:20

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:00

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 6'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:10', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '11d30afa-04a4-41b2-866f-5d5a2253eea7'	System	12 Aug 2020 23:21:27
User entered 'Yes (Y)'	System	12 Aug 2020 23:21:27

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:17', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '11d30afa-04a4-41b2-866f-5d5a2253eea7'	System	12 Aug 2020 23:21:27
User entered '98.6'	System	12 Aug 2020 23:21:27

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:21', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '11d30afa-04a4-41b2-866f-5d5a2253eea7'	System	12 Aug 2020 23:21:27
User entered 'No (N)'	System	12 Aug 2020 23:21:27

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:24', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '11d30afa-04a4-41b2-866f-5d5a2253eea7'	System	12 Aug 2020 23:21:27
User entered '12 Aug 2020 19:21'	System	12 Aug 2020 23:21:27

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 7'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:11:47', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'b7e24ad2-3939-4d84-bb82-08cef967ec5d'	System	14 Aug 2020 01:12:03
User entered 'Yes (Y)'	System	14 Aug 2020 01:12:03

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:11:55', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'b7e24ad2-3939-4d84-bb82-08cef967ec5d'	System	14 Aug 2020 01:12:03
User entered '98.9'	System	14 Aug 2020 01:12:03

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:11:59', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'b7e24ad2-3939-4d84-bb82-08cef967ec5d'	System	14 Aug 2020 01:12:03
User entered 'No (N)'	System	14 Aug 2020 01:12:03

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:02', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'b7e24ad2-3939-4d84-bb82-08cef967ec5d'	System	14 Aug 2020 01:12:03
User entered '13 Aug 2020 21:12'	System	14 Aug 2020 01:12:03

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-07T12:52:42', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '9970e4a5-293e-4a0c-bcae-cf180b5e7c39'	System	07 Aug 2020 16:53:24
User entered 'None (1)'	System	07 Aug 2020 16:53:24

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:52:48', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '9970e4a5-293e-4a0c-bcae-cf180b5e7c39'	System	07 Aug 2020 16:53:24
User entered 'No (N)'	System	07 Aug 2020 16:53:24

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:07', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '9970e4a5-293e-4a0c-bcae-cf180b5e7c39'	System	07 Aug 2020 16:53:24
User entered 'No (N)'	System	07 Aug 2020 16:53:24

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-07T12:53:17', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '9970e4a5-293e-4a0c-bcae-cf180b5e7c39'	System	07 Aug 2020 16:53:24
User entered 'None (1)'	System	07 Aug 2020 16:53:24

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:20', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '9970e4a5-293e-4a0c-bcae-cf180b5e7c39'	System	07 Aug 2020 16:53:24
User entered '07 Aug 2020 12:53'	System	07 Aug 2020 16:53:24

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:33'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 15:03'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-07T21:24:59', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'cbb33671-bf03-4290-81aa-6a9d350bb80a'	System	08 Aug 2020 01:25:55
User entered 'None (1)'	System	08 Aug 2020 01:25:55

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:25:40', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'cbb33671-bf03-4290-81aa-6a9d350bb80a'	System	08 Aug 2020 01:25:55
User entered 'No (N)'	System	08 Aug 2020 01:25:55

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:25:43', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'cbb33671-bf03-4290-81aa-6a9d350bb80a'	System	08 Aug 2020 01:25:55
User entered 'No (N)'	System	08 Aug 2020 01:25:55

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-07T21:25:51', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'cbb33671-bf03-4290-81aa-6a9d350bb80a'	System	08 Aug 2020 01:25:55
User entered 'None (1)'	System	08 Aug 2020 01:25:55

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:25:54', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'cbb33671-bf03-4290-81aa-6a9d350bb80a'	System	08 Aug 2020 01:25:55
User entered '07 Aug 2020 21:25'	System	08 Aug 2020 01:25:55

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 15:58'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 2'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-08T18:41:28', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '8607ae30-7c5d-42e4-928a-630a041fd65e'	System	08 Aug 2020 22:41:45
User entered 'None (1)'	System	08 Aug 2020 22:41:45

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:31', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '8607ae30-7c5d-42e4-928a-630a041fd65e'	System	08 Aug 2020 22:41:45
User entered 'No (N)'	System	08 Aug 2020 22:41:45

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:34', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '8607ae30-7c5d-42e4-928a-630a041fd65e'	System	08 Aug 2020 22:41:45
User entered 'No (N)'	System	08 Aug 2020 22:41:45

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-08T18:41:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '8607ae30-7c5d-42e4-928a-630a041fd65e'	System	08 Aug 2020 22:41:45
User entered 'None (1)'	System	08 Aug 2020 22:41:45

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:40', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '8607ae30-7c5d-42e4-928a-630a041fd65e'	System	08 Aug 2020 22:41:45
User entered '08 Aug 2020 18:41'	System	08 Aug 2020 22:41:45

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 3'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-09T19:20:53', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2db12d9b-c35d-46c3-a339-07ef91546585'	System	09 Aug 2020 23:21:07
User entered 'None (1)'	System	09 Aug 2020 23:21:07

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:20:56', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2db12d9b-c35d-46c3-a339-07ef91546585'	System	09 Aug 2020 23:21:07
User entered 'No (N)'	System	09 Aug 2020 23:21:07

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:20:59', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2db12d9b-c35d-46c3-a339-07ef91546585'	System	09 Aug 2020 23:21:07
User entered 'No (N)'	System	09 Aug 2020 23:21:07

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-09T19:21:02', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2db12d9b-c35d-46c3-a339-07ef91546585'	System	09 Aug 2020 23:21:07
User entered 'None (1)'	System	09 Aug 2020 23:21:07

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:21:04', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2db12d9b-c35d-46c3-a339-07ef91546585'	System	09 Aug 2020 23:21:07
User entered '09 Aug 2020 19:21'	System	09 Aug 2020 23:21:07

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 4'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-10T22:28:10', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'ed3afa65-3ad1-41fa-a9e6-163f0ec69e50'	System	11 Aug 2020 02:28:25
User entered 'None (1)'	System	11 Aug 2020 02:28:25

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'ed3afa65-3ad1-41fa-a9e6-163f0ec69e50'	System	11 Aug 2020 02:28:25
User entered 'No (N)'	System	11 Aug 2020 02:28:25

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:15', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'ed3afa65-3ad1-41fa-a9e6-163f0ec69e50'	System	11 Aug 2020 02:28:25
User entered 'No (N)'	System	11 Aug 2020 02:28:25

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-10T22:28:19', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'ed3afa65-3ad1-41fa-a9e6-163f0ec69e50'	System	11 Aug 2020 02:28:25
User entered 'None (1)'	System	11 Aug 2020 02:28:25

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:21', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'ed3afa65-3ad1-41fa-a9e6-163f0ec69e50'	System	11 Aug 2020 02:28:25
User entered '10 Aug 2020 22:28'	System	11 Aug 2020 02:28:25

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 5'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-11T20:45:22', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '15f2d634-b103-4a49-bb07-622ee93e0a32'	System	12 Aug 2020 00:45:39
User entered 'None (1)'	System	12 Aug 2020 00:45:39

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:25', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '15f2d634-b103-4a49-bb07-622ee93e0a32'	System	12 Aug 2020 00:45:39
User entered 'No (N)'	System	12 Aug 2020 00:45:39

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:29', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '15f2d634-b103-4a49-bb07-622ee93e0a32'	System	12 Aug 2020 00:45:39
User entered 'No (N)'	System	12 Aug 2020 00:45:39

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-11T20:45:35', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '15f2d634-b103-4a49-bb07-622ee93e0a32'	System	12 Aug 2020 00:45:39
User entered 'None (1)'	System	12 Aug 2020 00:45:39

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '15f2d634-b103-4a49-bb07-622ee93e0a32'	System	12 Aug 2020 00:45:39
User entered '11 Aug 2020 20:45'	System	12 Aug 2020 00:45:39

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 6'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-12T19:21:30', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '6dcaae-3037-4236-9558-249af9d91753'	System	12 Aug 2020 23:21:43
User entered 'None (1)'	System	12 Aug 2020 23:21:43

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:33', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '6dcaae-3037-4236-9558-249af9d91753'	System	12 Aug 2020 23:21:43
User entered 'No (N)'	System	12 Aug 2020 23:21:43

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:36', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '6dcaae-3037-4236-9558-249af9d91753'	System	12 Aug 2020 23:21:43
User entered 'No (N)'	System	12 Aug 2020 23:21:43

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-12T19:21:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '6dcaae-e3037-4236-9558-249af9d91753'	System	12 Aug 2020 23:21:43
User entered 'None (1)'	System	12 Aug 2020 23:21:43

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:40', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '6dcaae-3037-4236-9558-249af9d91753'	System	12 Aug 2020 23:21:43
User entered '12 Aug 2020 19:21'	System	12 Aug 2020 23:21:43

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 7'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-13T21:12:08', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86abb68f-afc4-4943-bf1b-91bcf74ff381'	System	14 Aug 2020 01:12:21
User entered 'None (1)'	System	14 Aug 2020 01:12:21

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:11', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86abb68f-afc4-4943-bf1b-91bcf74ff381'	System	14 Aug 2020 01:12:21
User entered 'No (N)'	System	14 Aug 2020 01:12:21

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86abb68f-afc4-4943-bf1b-91bcf74ff381'	System	14 Aug 2020 01:12:21
User entered 'No (N)'	System	14 Aug 2020 01:12:21

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-13T21:12:15', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86abb68f-afc4-4943-bf1b-91bcf74ff381'	System	14 Aug 2020 01:12:21
User entered 'None (1)'	System	14 Aug 2020 01:12:21

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:18', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86abb68f-afc4-4943-bf1b-91bcf74ff381'	System	14 Aug 2020 01:12:21
User entered '13 Aug 2020 21:12'	System	14 Aug 2020 01:12:21

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:26', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e79b881c-48e7-4cc1-8976-e7ff42b1ef48'	System	07 Aug 2020 16:53:52
User entered 'None (0)'	System	07 Aug 2020 16:53:52

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:29', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e79b881c-48e7-4cc1-8976-e7ff42b1ef48'	System	07 Aug 2020 16:53:52
User entered 'None (0)'	System	07 Aug 2020 16:53:52

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:33', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e79b881c-48e7-4cc1-8976-e7ff42b1ef48'	System	07 Aug 2020 16:53:52
User entered 'None (0)'	System	07 Aug 2020 16:53:52

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:36', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e79b881c-48e7-4cc1-8976-e7ff42b1ef48'	System	07 Aug 2020 16:53:52
User entered 'None (0)'	System	07 Aug 2020 16:53:52

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e79b881c-48e7-4cc1-8976-e7ff42b1ef48'	System	07 Aug 2020 16:53:52
User entered 'None (0)'	System	07 Aug 2020 16:53:52

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:41', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e79b881c-48e7-4cc1-8976-e7ff42b1ef48'	System	07 Aug 2020 16:53:52
User entered 'None (0)'	System	07 Aug 2020 16:53:52

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-07T12:53:48', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e79b881c-48e7-4cc1-8976-e7ff42b1ef48'	System	07 Aug 2020 16:53:52
User entered 'No (N)'	System	07 Aug 2020 16:53:52

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T12:53:51', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e79b881c-48e7-4cc1-8976-e7ff42b1ef48'	System	07 Aug 2020 16:53:52
User entered '07 Aug 2020 12:53'	System	07 Aug 2020 16:53:52

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:33'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 15:03'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:26:04', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2c1cf5ee-6292-4218-bf7b-a2ae49a15472'	System	08 Aug 2020 01:26:38
User entered 'None (0)'	System	08 Aug 2020 01:26:38

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:26:07', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2c1cf5ee-6292-4218-bf7b-a2ae49a15472'	System	08 Aug 2020 01:26:38
User entered 'None (0)'	System	08 Aug 2020 01:26:38

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:26:15', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2c1cf5ee-6292-4218-bf7b-a2ae49a15472'	System	08 Aug 2020 01:26:38
User entered 'None (0)'	System	08 Aug 2020 01:26:38

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:26:19', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2c1cf5ee-6292-4218-bf7b-a2ae49a15472'	System	08 Aug 2020 01:26:38
User entered 'None (0)'	System	08 Aug 2020 01:26:38

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:26:22', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2c1cf5ee-6292-4218-bf7b-a2ae49a15472'	System	08 Aug 2020 01:26:38
User entered 'None (0)'	System	08 Aug 2020 01:26:38

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:26:25', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2c1cf5ee-6292-4218-bf7b-a2ae49a15472'	System	08 Aug 2020 01:26:38
User entered 'None (0)'	System	08 Aug 2020 01:26:38

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-07T21:26:33', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2c1cf5ee-6292-4218-bf7b-a2ae49a15472'	System	08 Aug 2020 01:26:38
User entered 'No (N)'	System	08 Aug 2020 01:26:38

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-07T21:26:35', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '2c1cf5ee-6292-4218-bf7b-a2ae49a15472'	System	08 Aug 2020 01:26:38
User entered '07 Aug 2020 21:26'	System	08 Aug 2020 01:26:38

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 15:58'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 2'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:44', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd973fdc0-3920-4cdb-9aa6-d2e0de5633a8'	System	08 Aug 2020 22:42:15
User entered 'None (0)'	System	08 Aug 2020 22:42:15

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:48', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd973fdc0-3920-4cdb-9aa6-d2e0de5633a8'	System	08 Aug 2020 22:42:15
User entered 'None (0)'	System	08 Aug 2020 22:42:15

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:41:53', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd973fdc0-3920-4cdb-9aa6-d2e0de5633a8'	System	08 Aug 2020 22:42:15
User entered 'None (0)'	System	08 Aug 2020 22:42:15

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:42:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd973fdc0-3920-4cdb-9aa6-d2e0de5633a8'	System	08 Aug 2020 22:42:15
User entered 'None (0)'	System	08 Aug 2020 22:42:15

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:42:03', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd973fdc0-3920-4cdb-9aa6-d2e0de5633a8'	System	08 Aug 2020 22:42:15
User entered 'None (0)'	System	08 Aug 2020 22:42:15

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:42:05', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd973fdc0-3920-4cdb-9aa6-d2e0de5633a8'	System	08 Aug 2020 22:42:15
User entered 'None (0)'	System	08 Aug 2020 22:42:15

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-08T18:42:10', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd973fdc0-3920-4cdb-9aa6-d2e0de5633a8'	System	08 Aug 2020 22:42:15
User entered 'No (N)'	System	08 Aug 2020 22:42:15

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-08T18:42:12', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd973fdc0-3920-4cdb-9aa6-d2e0de5633a8'	System	08 Aug 2020 22:42:15
User entered '08 Aug 2020 18:42'	System	08 Aug 2020 22:42:15

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 3'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:21:09', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd5855f6f-cc94-4c60-b6db-36f9e26ff5cb'	System	09 Aug 2020 23:21:31
User entered 'None (0)'	System	09 Aug 2020 23:21:31

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:21:11', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd5855f6f-cc94-4c60-b6db-36f9e26ff5cb'	System	09 Aug 2020 23:21:31
User entered 'None (0)'	System	09 Aug 2020 23:21:31

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:21:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd5855f6f-cc94-4c60-b6db-36f9e26ff5cb'	System	09 Aug 2020 23:21:31
User entered 'None (0)'	System	09 Aug 2020 23:21:31

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:21:15', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd5855f6f-cc94-4c60-b6db-36f9e26ff5cb'	System	09 Aug 2020 23:21:31
User entered 'None (0)'	System	09 Aug 2020 23:21:31

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:21:18', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd5855f6f-cc94-4c60-b6db-36f9e26ff5cb'	System	09 Aug 2020 23:21:31
User entered 'None (0)'	System	09 Aug 2020 23:21:31

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:21:21', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd5855f6f-cc94-4c60-b6db-36f9e26ff5cb'	System	09 Aug 2020 23:21:31
User entered 'None (0)'	System	09 Aug 2020 23:21:31

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-09T19:21:24', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd5855f6f-cc94-4c60-b6db-36f9e26ff5cb'	System	09 Aug 2020 23:21:31
User entered 'No (N)'	System	09 Aug 2020 23:21:31

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-09T19:21:26', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd5855f6f-cc94-4c60-b6db-36f9e26ff5cb'	System	09 Aug 2020 23:21:31
User entered '09 Aug 2020 19:21'	System	09 Aug 2020 23:21:31

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 4'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:26', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '445dbdad-20dc-49aa-a4c3-b5812d616395'	System	11 Aug 2020 02:28:47
User entered 'None (0)'	System	11 Aug 2020 02:28:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:28', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '445dbdad-20dc-49aa-a4c3-b5812d616395'	System	11 Aug 2020 02:28:47
User entered 'None (0)'	System	11 Aug 2020 02:28:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:31', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '445dbdad-20dc-49aa-a4c3-b5812d616395'	System	11 Aug 2020 02:28:47
User entered 'None (0)'	System	11 Aug 2020 02:28:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:33', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '445dbdad-20dc-49aa-a4c3-b5812d616395'	System	11 Aug 2020 02:28:47
User entered 'None (0)'	System	11 Aug 2020 02:28:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:36', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '445dbdad-20dc-49aa-a4c3-b5812d616395'	System	11 Aug 2020 02:28:47
User entered 'None (0)'	System	11 Aug 2020 02:28:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '445dbdad-20dc-49aa-a4c3-b5812d616395'	System	11 Aug 2020 02:28:47
User entered 'None (0)'	System	11 Aug 2020 02:28:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-10T22:28:41', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '445dbdad-20dc-49aa-a4c3-b5812d616395'	System	11 Aug 2020 02:28:47
User entered 'No (N)'	System	11 Aug 2020 02:28:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-10T22:28:44', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '445dbdad-20dc-49aa-a4c3-b5812d616395'	System	11 Aug 2020 02:28:47
User entered '10 Aug 2020 22:28'	System	11 Aug 2020 02:28:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 5'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:46', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dd7d4b52-606f-41bc-8586-b4d0d0cc1712'	System	12 Aug 2020 00:46:14
User entered 'None (0)'	System	12 Aug 2020 00:46:14

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:49', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dd7d4b52-606f-41bc-8586-b4d0d0cc1712'	System	12 Aug 2020 00:46:14
User entered 'None (0)'	System	12 Aug 2020 00:46:14

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:51', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dd7d4b52-606f-41bc-8586-b4d0d0cc1712'	System	12 Aug 2020 00:46:14
User entered 'None (0)'	System	12 Aug 2020 00:46:14

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:55', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dd7d4b52-606f-41bc-8586-b4d0d0cc1712'	System	12 Aug 2020 00:46:14
User entered 'None (0)'	System	12 Aug 2020 00:46:14

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:45:59', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dd7d4b52-606f-41bc-8586-b4d0d0cc1712'	System	12 Aug 2020 00:46:14
User entered 'None (0)'	System	12 Aug 2020 00:46:14

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:46:02', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dd7d4b52-606f-41bc-8586-b4d0d0cc1712'	System	12 Aug 2020 00:46:14
User entered 'None (0)'	System	12 Aug 2020 00:46:14

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-11T20:46:09', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dd7d4b52-606f-41bc-8586-b4d0d0cc1712'	System	12 Aug 2020 00:46:14
User entered 'No (N)'	System	12 Aug 2020 00:46:14

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-11T20:46:11', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'dd7d4b52-606f-41bc-8586-b4d0d0cc1712'	System	12 Aug 2020 00:46:14
User entered '11 Aug 2020 20:46'	System	12 Aug 2020 00:46:14

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 6'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:47', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86bd0542-f8ef-4773-a258-e1657822d9d4'	System	12 Aug 2020 23:22:05
User entered 'None (0)'	System	12 Aug 2020 23:22:05

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:49', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86bd0542-f8ef-4773-a258-e1657822d9d4'	System	12 Aug 2020 23:22:05
User entered 'None (0)'	System	12 Aug 2020 23:22:05

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:52', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86bd0542-f8ef-4773-a258-e1657822d9d4'	System	12 Aug 2020 23:22:05
User entered 'None (0)'	System	12 Aug 2020 23:22:05

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:54', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86bd0542-f8ef-4773-a258-e1657822d9d4'	System	12 Aug 2020 23:22:05
User entered 'None (0)'	System	12 Aug 2020 23:22:05

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:56', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86bd0542-f8ef-4773-a258-e1657822d9d4'	System	12 Aug 2020 23:22:05
User entered 'None (0)'	System	12 Aug 2020 23:22:05

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:21:58', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86bd0542-f8ef-4773-a258-e1657822d9d4'	System	12 Aug 2020 23:22:05
User entered 'None (0)'	System	12 Aug 2020 23:22:05

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-12T19:22:02', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86bd0542-f8ef-4773-a258-e1657822d9d4'	System	12 Aug 2020 23:22:05
User entered 'No (N)'	System	12 Aug 2020 23:22:05

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-12T19:22:04', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '86bd0542-f8ef-4773-a258-e1657822d9d4'	System	12 Aug 2020 23:22:05
User entered '12 Aug 2020 19:22'	System	12 Aug 2020 23:22:05

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 7'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:24', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd3f78e6d-68ea-40cf-975a-ab7de29f9ed8'	System	14 Aug 2020 01:12:47
User entered 'None (0)'	System	14 Aug 2020 01:12:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:26', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd3f78e6d-68ea-40cf-975a-ab7de29f9ed8'	System	14 Aug 2020 01:12:47
User entered 'None (0)'	System	14 Aug 2020 01:12:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:28', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd3f78e6d-68ea-40cf-975a-ab7de29f9ed8'	System	14 Aug 2020 01:12:47
User entered 'None (0)'	System	14 Aug 2020 01:12:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:31', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd3f78e6d-68ea-40cf-975a-ab7de29f9ed8'	System	14 Aug 2020 01:12:47
User entered 'None (0)'	System	14 Aug 2020 01:12:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:33', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd3f78e6d-68ea-40cf-975a-ab7de29f9ed8'	System	14 Aug 2020 01:12:47
User entered 'None (0)'	System	14 Aug 2020 01:12:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:36', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd3f78e6d-68ea-40cf-975a-ab7de29f9ed8'	System	14 Aug 2020 01:12:47
User entered 'None (0)'	System	14 Aug 2020 01:12:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-08-13T21:12:41', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd3f78e6d-68ea-40cf-975a-ab7de29f9ed8'	System	14 Aug 2020 01:12:47
User entered 'No (N)'	System	14 Aug 2020 01:12:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-08-13T21:12:44', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd3f78e6d-68ea-40cf-975a-ab7de29f9ed8'	System	14 Aug 2020 01:12:47
User entered '13 Aug 2020 21:12'	System	14 Aug 2020 01:12:47

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 16:31:32

US3372060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	26 Aug 2020 15:16:59

US3372060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '17 Aug 2020'	Alexandra Arango (b) (4) (b) (4)	26 Aug 2020 15:16:59

US3372060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	26 Aug 2020 15:16:59

US3372060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	26 Aug 2020 15:16:59

US3372060

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	21 Aug 2020 20:28:57

US3372060

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 20:28:57

US3372060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	21 Aug 2020 20:29:09

US3372060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '21 Aug 2020'	Alexandra Arango (b) (4) (b) (4)	21 Aug 2020 20:29:09

US3372060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	21 Aug 2020 20:29:09

US3372060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	21 Aug 2020 20:29:09

US3372060

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	21 Aug 2020 20:29:15

US3372060

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 20:29:15

US3372060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	03 Sep 2020 18:08:11

US3372060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Alexandra Arango (b) (4) (b) (4)	03 Sep 2020 18:08:11

US3372060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	03 Sep 2020 18:08:11

US3372060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	03 Sep 2020 18:08:11

US3372060

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	03 Sep 2020 18:08:16

US3372060

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 18:08:16

US3372060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:42:51

US3372060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 15:42:51

US3372060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Sep 2020 15:42:51

US3372060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	10 Sep 2020 15:42:51

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '10:34'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 10:34'	System	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '77'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '14'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '119'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '74'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Sep 2020 16:30:55

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '12:11'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:11'	System	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '83'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '14'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '127'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '84' reason for change: Data Entry Error	Peter Jacob (b) (4)	15 Sep 2020 16:31:22
User entered '74'	Peter Jacob (b) (4)	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Sep 2020 16:31:18

US3372060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:00

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:30

US3372060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:30

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '11:34'	(b) (4), (b) (6)	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:34'	System	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 15:43:17

US3372060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:41

US3372060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:41

US3372060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '10:58'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:41

US3372060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 10:58'	System	15 Sep 2020 16:31:41

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:02:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:50

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:02:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:50

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:02:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:50

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:02:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:57'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:50

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 10:57'	System	15 Sep 2020 16:31:50

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:02:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:50

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:02:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:50

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:02:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Sep 2020 16:31:50

US3372060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 16:31:50

US3372060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	10 Sep 2020 17:17:28

US3372060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:17:28

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:10:27', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '3613aa70-6268-4bb9-9e7b-07f97a95a8b5'	System	10 Sep 2020 16:10:43
User entered 'Yes (Y)'	System	10 Sep 2020 16:10:43

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:10:33', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '3613aa70-6268-4bb9-9e7b-07f97a95a8b5'	System	10 Sep 2020 16:10:43
User entered '98.1'	System	10 Sep 2020 16:10:43

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:10:37', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '3613aa70-6268-4bb9-9e7b-07f97a95a8b5'	System	10 Sep 2020 16:10:43
User entered 'No (N)'	System	10 Sep 2020 16:10:43

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:10:40', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '3613aa70-6268-4bb9-9e7b-07f97a95a8b5'	System	10 Sep 2020 16:10:43
User entered '10 Sep 2020 12:10'	System	10 Sep 2020 16:10:43

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:54'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 14:24'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:47:29', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'ae0b690d-0698-4d1e-bae5-2dde12024496'	System	10 Sep 2020 23:48:09
User entered 'Yes (Y)'	System	10 Sep 2020 23:48:09

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:47:37', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'ae0b690d-0698-4d1e-bae5-2dde12024496'	System	10 Sep 2020 23:48:09
User entered '98.3'	System	10 Sep 2020 23:48:09

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:48:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'ae0b690d-0698-4d1e-bae5-2dde12024496'	System	10 Sep 2020 23:48:09
User entered 'No (N)'	System	10 Sep 2020 23:48:09

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:48:04', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'ae0b690d-0698-4d1e-bae5-2dde12024496'	System	10 Sep 2020 23:48:09
User entered '10 Sep 2020 19:48'	System	10 Sep 2020 23:48:09

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:19'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 2'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '517260d8-9acc-447e-84ab-081d76b3eebd'	System	11 Sep 2020 22:32:55
User entered 'Yes (Y)'	System	11 Sep 2020 22:32:55

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:20', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '517260d8-9acc-447e-84ab-081d76b3eebd'	System	11 Sep 2020 22:32:55
User entered '98.8'	System	11 Sep 2020 22:32:55

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:24', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '517260d8-9acc-447e-84ab-081d76b3eebd'	System	11 Sep 2020 22:32:55
User entered 'No (N)'	System	11 Sep 2020 22:32:55

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:26', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '517260d8-9acc-447e-84ab-081d76b3eebd'	System	11 Sep 2020 22:32:55
User entered '11 Sep 2020 18:32'	System	11 Sep 2020 22:32:55

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 3'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:31', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0c6f7569-5eba-4730-b852-7a9dae61a16f'	System	13 Sep 2020 02:15:58
User entered 'Yes (Y)'	System	13 Sep 2020 02:15:58

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0c6f7569-5eba-4730-b852-7a9dae61a16f'	System	13 Sep 2020 02:15:58
User entered '98.3'	System	13 Sep 2020 02:15:58

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:41', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0c6f7569-5eba-4730-b852-7a9dae61a16f'	System	13 Sep 2020 02:15:58
User entered 'No (N)'	System	13 Sep 2020 02:15:58

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:44', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0c6f7569-5eba-4730-b852-7a9dae61a16f'	System	13 Sep 2020 02:15:58
User entered '12 Sep 2020 22:15'	System	13 Sep 2020 02:15:58

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 4'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:40:14', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'eeb9f6e7-1583-445e-9c39-0955ae1f54d9'	System	14 Sep 2020 02:40:47
User entered 'Yes (Y)'	System	14 Sep 2020 02:40:47

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:40:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'eeb9f6e7-1583-445e-9c39-0955ae1f54d9'	System	14 Sep 2020 02:40:47
User entered '97.0'	System	14 Sep 2020 02:40:47

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:40:42', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'eeb9f6e7-1583-445e-9c39-0955ae1f54d9'	System	14 Sep 2020 02:40:47
User entered 'No (N)'	System	14 Sep 2020 02:40:47

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:40:45', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'eeb9f6e7-1583-445e-9c39-0955ae1f54d9'	System	14 Sep 2020 02:40:47
User entered '13 Sep 2020 22:40'	System	14 Sep 2020 02:40:47

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 5'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:38:27', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e7b29902-efd8-48f7-9417-a2dbd485d60f'	System	15 Sep 2020 13:38:40
User entered 'Yes (Y)'	System	15 Sep 2020 13:38:40

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:38:33', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e7b29902-efd8-48f7-9417-a2dbd485d60f'	System	15 Sep 2020 13:38:40
User entered '98.5'	System	15 Sep 2020 13:38:40

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:38:37', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e7b29902-efd8-48f7-9417-a2dbd485d60f'	System	15 Sep 2020 13:38:40
User entered 'No (N)'	System	15 Sep 2020 13:38:40

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:38:40', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e7b29902-efd8-48f7-9417-a2dbd485d60f'	System	15 Sep 2020 13:38:40
User entered '15 Sep 2020 09:38'	System	15 Sep 2020 13:38:40

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 6'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:29:14', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8e650f9-25de-4cbc-885d-ba0b0d65182b'	System	16 Sep 2020 01:29:34
User entered 'Yes (Y)'	System	16 Sep 2020 01:29:34

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:29:21', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8e650f9-25de-4cbc-885d-ba0b0d65182b'	System	16 Sep 2020 01:29:34
User entered '94.3'	System	16 Sep 2020 01:29:34

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:29:27', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8e650f9-25de-4cbc-885d-ba0b0d65182b'	System	16 Sep 2020 01:29:34
User entered 'No (N)'	System	16 Sep 2020 01:29:34

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:29:31', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8e650f9-25de-4cbc-885d-ba0b0d65182b'	System	16 Sep 2020 01:29:34
User entered '15 Sep 2020 21:29'	System	16 Sep 2020 01:29:34

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 7'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:38:16', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5d843dd6-c1fc-4e59-8967-e57cd6479d4e'	System	17 Sep 2020 00:38:33
User entered 'Yes (Y)'	System	17 Sep 2020 00:38:33

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:38:25', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5d843dd6-c1fc-4e59-8967-e57cd6479d4e'	System	17 Sep 2020 00:38:33
User entered '99.3'	System	17 Sep 2020 00:38:33

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:38:28', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5d843dd6-c1fc-4e59-8967-e57cd6479d4e'	System	17 Sep 2020 00:38:33
User entered 'No (N)'	System	17 Sep 2020 00:38:33

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:38:31', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5d843dd6-c1fc-4e59-8967-e57cd6479d4e'	System	17 Sep 2020 00:38:33
User entered '16 Sep 2020 20:38'	System	17 Sep 2020 00:38:33

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-10T12:11:05', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7d9a38ab-578e-4ca4-8686-23f1a6d0b839'	System	10 Sep 2020 16:11:22
User entered 'None (1)'	System	10 Sep 2020 16:11:22

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:07', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7d9a38ab-578e-4ca4-8686-23f1a6d0b839'	System	10 Sep 2020 16:11:22
User entered 'No (N)'	System	10 Sep 2020 16:11:22

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:10', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7d9a38ab-578e-4ca4-8686-23f1a6d0b839'	System	10 Sep 2020 16:11:22
User entered 'No (N)'	System	10 Sep 2020 16:11:22

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-10T12:11:18', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7d9a38ab-578e-4ca4-8686-23f1a6d0b839'	System	10 Sep 2020 16:11:22
User entered 'None (1)'	System	10 Sep 2020 16:11:22

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:20', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7d9a38ab-578e-4ca4-8686-23f1a6d0b839'	System	10 Sep 2020 16:11:22
User entered '10 Sep 2020 12:11'	System	10 Sep 2020 16:11:22

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:54'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 14:24'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-10T19:48:23', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7edfb30e-34f6-417a-947e-3bb7dcdbbffe'	System	10 Sep 2020 23:48:44
User entered 'None (1)'	System	10 Sep 2020 23:48:44

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:48:27', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7edfb30e-34f6-417a-947e-3bb7dcdbbffe'	System	10 Sep 2020 23:48:44
User entered 'No (N)'	System	10 Sep 2020 23:48:44

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:48:30', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7edfb30e-34f6-417a-947e-3bb7dcdbbffe'	System	10 Sep 2020 23:48:44
User entered 'No (N)'	System	10 Sep 2020 23:48:44

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-10T19:48:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7edfb30e-34f6-417a-947e-3bb7dcdbbffe'	System	10 Sep 2020 23:48:44
User entered 'None (1)'	System	10 Sep 2020 23:48:44

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:48:40', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '7edfb30e-34f6-417a-947e-3bb7dcdbbffe'	System	10 Sep 2020 23:48:44
User entered '10 Sep 2020 19:48'	System	10 Sep 2020 23:48:44

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:19'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 2'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-11T18:32:32', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd9860c23-fc80-44c3-ab86-1b88c91b2f3d'	System	11 Sep 2020 22:33:01
User entered 'None (1)'	System	11 Sep 2020 22:33:01

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:34', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd9860c23-fc80-44c3-ab86-1b88c91b2f3d'	System	11 Sep 2020 22:33:01
User entered 'No (N)'	System	11 Sep 2020 22:33:01

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd9860c23-fc80-44c3-ab86-1b88c91b2f3d'	System	11 Sep 2020 22:33:01
User entered 'No (N)'	System	11 Sep 2020 22:33:01

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-11T18:32:42', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd9860c23-fc80-44c3-ab86-1b88c91b2f3d'	System	11 Sep 2020 22:33:01
User entered 'None (1)'	System	11 Sep 2020 22:33:01

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:44', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd9860c23-fc80-44c3-ab86-1b88c91b2f3d'	System	11 Sep 2020 22:33:01
User entered '11 Sep 2020 18:32'	System	11 Sep 2020 22:33:01

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 3'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-12T22:14:50', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '51abfc68-4a75-4508-ad51-e0d8be63ee7f'	System	13 Sep 2020 02:15:49
User entered 'None (1)'	System	13 Sep 2020 02:15:49

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:14:57', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '51abfc68-4a75-4508-ad51-e0d8be63ee7f'	System	13 Sep 2020 02:15:49
User entered 'No (N)'	System	13 Sep 2020 02:15:49

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '51abfc68-4a75-4508-ad51-e0d8be63ee7f'	System	13 Sep 2020 02:15:49
User entered 'No (N)'	System	13 Sep 2020 02:15:49

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-12T22:15:09', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '51abfc68-4a75-4508-ad51-e0d8be63ee7f'	System	13 Sep 2020 02:15:49
User entered 'None (1)'	System	13 Sep 2020 02:15:49

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:11', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '51abfc68-4a75-4508-ad51-e0d8be63ee7f'	System	13 Sep 2020 02:15:49
User entered '12 Sep 2020 22:15'	System	13 Sep 2020 02:15:49

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 4'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-13T22:41:02', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'a49add26-3882-4e57-9948-2ca3059e0b41'	System	14 Sep 2020 02:41:14
User entered 'None (1)'	System	14 Sep 2020 02:41:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:05', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'a49add26-3882-4e57-9948-2ca3059e0b41'	System	14 Sep 2020 02:41:14
User entered 'No (N)'	System	14 Sep 2020 02:41:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:08', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'a49add26-3882-4e57-9948-2ca3059e0b41'	System	14 Sep 2020 02:41:14
User entered 'No (N)'	System	14 Sep 2020 02:41:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-13T22:41:11', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'a49add26-3882-4e57-9948-2ca3059e0b41'	System	14 Sep 2020 02:41:14
User entered 'None (1)'	System	14 Sep 2020 02:41:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'a49add26-3882-4e57-9948-2ca3059e0b41'	System	14 Sep 2020 02:41:14
User entered '13 Sep 2020 22:41'	System	14 Sep 2020 02:41:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 5'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-15T09:38:46', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '096f6786-19ee-471c-9437-a66cba76a912'	System	15 Sep 2020 13:38:55
User entered 'None (1)'	System	15 Sep 2020 13:38:55

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:38:48', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '096f6786-19ee-471c-9437-a66cba76a912'	System	15 Sep 2020 13:38:55
User entered 'No (N)'	System	15 Sep 2020 13:38:55

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:38:51', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '096f6786-19ee-471c-9437-a66cba76a912'	System	15 Sep 2020 13:38:55
User entered 'No (N)'	System	15 Sep 2020 13:38:55

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-15T09:38:53', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '096f6786-19ee-471c-9437-a66cba76a912'	System	15 Sep 2020 13:38:55
User entered 'None (1)'	System	15 Sep 2020 13:38:55

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:38:55', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '096f6786-19ee-471c-9437-a66cba76a912'	System	15 Sep 2020 13:38:55
User entered '15 Sep 2020 09:38'	System	15 Sep 2020 13:38:55

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 6'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-15T21:29:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'df4c5b63-8591-4b53-8a54-de5ff5ad60d2'	System	16 Sep 2020 01:30:14
User entered 'None (1)'	System	16 Sep 2020 01:30:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:29:43', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'df4c5b63-8591-4b53-8a54-de5ff5ad60d2'	System	16 Sep 2020 01:30:14
User entered 'No (N)'	System	16 Sep 2020 01:30:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:02', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'df4c5b63-8591-4b53-8a54-de5ff5ad60d2'	System	16 Sep 2020 01:30:14
User entered 'No (N)'	System	16 Sep 2020 01:30:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-15T21:30:05', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'df4c5b63-8591-4b53-8a54-de5ff5ad60d2'	System	16 Sep 2020 01:30:14
User entered 'None (1)'	System	16 Sep 2020 01:30:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'df4c5b63-8591-4b53-8a54-de5ff5ad60d2'	System	16 Sep 2020 01:30:14
User entered '15 Sep 2020 21:30'	System	16 Sep 2020 01:30:14

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 7'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-16T20:38:36', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '935ae91b-9ee4-4825-9372-8e95b6b67f5f'	System	17 Sep 2020 00:38:57
User entered 'None (1)'	System	17 Sep 2020 00:38:57

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:38:44', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '935ae91b-9ee4-4825-9372-8e95b6b67f5f'	System	17 Sep 2020 00:38:57
User entered 'No (N)'	System	17 Sep 2020 00:38:57

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:38:47', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '935ae91b-9ee4-4825-9372-8e95b6b67f5f'	System	17 Sep 2020 00:38:57
User entered 'No (N)'	System	17 Sep 2020 00:38:57

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-16T20:38:54', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '935ae91b-9ee4-4825-9372-8e95b6b67f5f'	System	17 Sep 2020 00:38:57
User entered 'None (1)'	System	17 Sep 2020 00:38:57

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:38:56', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '935ae91b-9ee4-4825-9372-8e95b6b67f5f'	System	17 Sep 2020 00:38:57
User entered '16 Sep 2020 20:38'	System	17 Sep 2020 00:38:57

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:25', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5b62abfe-d60e-489e-83ad-ad90a0c4142a'	System	10 Sep 2020 16:11:47
User entered 'None (0)'	System	10 Sep 2020 16:11:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:27', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5b62abfe-d60e-489e-83ad-ad90a0c4142a'	System	10 Sep 2020 16:11:47
User entered 'None (0)'	System	10 Sep 2020 16:11:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:30', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5b62abfe-d60e-489e-83ad-ad90a0c4142a'	System	10 Sep 2020 16:11:47
User entered 'None (0)'	System	10 Sep 2020 16:11:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:33', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5b62abfe-d60e-489e-83ad-ad90a0c4142a'	System	10 Sep 2020 16:11:47
User entered 'None (0)'	System	10 Sep 2020 16:11:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:36', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5b62abfe-d60e-489e-83ad-ad90a0c4142a'	System	10 Sep 2020 16:11:47
User entered 'None (0)'	System	10 Sep 2020 16:11:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:39', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5b62abfe-d60e-489e-83ad-ad90a0c4142a'	System	10 Sep 2020 16:11:47
User entered 'None (0)'	System	10 Sep 2020 16:11:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-10T12:11:43', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5b62abfe-d60e-489e-83ad-ad90a0c4142a'	System	10 Sep 2020 16:11:47
User entered 'No (N)'	System	10 Sep 2020 16:11:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T12:11:45', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5b62abfe-d60e-489e-83ad-ad90a0c4142a'	System	10 Sep 2020 16:11:47
User entered '10 Sep 2020 12:11'	System	10 Sep 2020 16:11:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:54'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 14:24'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:49:01', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e39b7186-44b5-4121-87ea-f96ba4c6a916'	System	10 Sep 2020 23:49:30
User entered 'None (0)'	System	10 Sep 2020 23:49:30

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:49:04', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e39b7186-44b5-4121-87ea-f96ba4c6a916'	System	10 Sep 2020 23:49:30
User entered 'None (0)'	System	10 Sep 2020 23:49:30

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:49:07', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e39b7186-44b5-4121-87ea-f96ba4c6a916'	System	10 Sep 2020 23:49:30
User entered 'None (0)'	System	10 Sep 2020 23:49:30

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:49:11', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e39b7186-44b5-4121-87ea-f96ba4c6a916'	System	10 Sep 2020 23:49:30
User entered 'None (0)'	System	10 Sep 2020 23:49:30

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:49:14', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e39b7186-44b5-4121-87ea-f96ba4c6a916'	System	10 Sep 2020 23:49:30
User entered 'None (0)'	System	10 Sep 2020 23:49:30

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:49:17', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e39b7186-44b5-4121-87ea-f96ba4c6a916'	System	10 Sep 2020 23:49:30
User entered 'None (0)'	System	10 Sep 2020 23:49:30

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-10T19:49:22', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e39b7186-44b5-4121-87ea-f96ba4c6a916'	System	10 Sep 2020 23:49:30
User entered 'No (N)'	System	10 Sep 2020 23:49:30

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-10T19:49:24', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e39b7186-44b5-4121-87ea-f96ba4c6a916'	System	10 Sep 2020 23:49:30
User entered '10 Sep 2020 19:49'	System	10 Sep 2020 23:49:30

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:19'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 2'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:49', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '45073f3f-2a69-4685-8d04-0006060e9b56'	System	11 Sep 2020 22:33:22
User entered 'None (0)'	System	11 Sep 2020 22:33:22

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:53', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '45073f3f-2a69-4685-8d04-0006060e9b56'	System	11 Sep 2020 22:33:22
User entered 'None (0)'	System	11 Sep 2020 22:33:22

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:32:56', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '45073f3f-2a69-4685-8d04-0006060e9b56'	System	11 Sep 2020 22:33:22
User entered 'None (0)'	System	11 Sep 2020 22:33:22

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:33:00', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '45073f3f-2a69-4685-8d04-0006060e9b56'	System	11 Sep 2020 22:33:22
User entered 'None (0)'	System	11 Sep 2020 22:33:22

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:33:04', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '45073f3f-2a69-4685-8d04-0006060e9b56'	System	11 Sep 2020 22:33:22
User entered 'None (0)'	System	11 Sep 2020 22:33:22

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:33:07', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '45073f3f-2a69-4685-8d04-0006060e9b56'	System	11 Sep 2020 22:33:22
User entered 'None (0)'	System	11 Sep 2020 22:33:22

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-11T18:33:12', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '45073f3f-2a69-4685-8d04-0006060e9b56'	System	11 Sep 2020 22:33:22
User entered 'No (N)'	System	11 Sep 2020 22:33:22

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-11T18:33:15', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '45073f3f-2a69-4685-8d04-0006060e9b56'	System	11 Sep 2020 22:33:22
User entered '11 Sep 2020 18:33'	System	11 Sep 2020 22:33:22

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 3'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:52', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e648112d-7d2c-4e72-9bea-252d480f826b'	System	13 Sep 2020 02:16:15
User entered 'None (0)'	System	13 Sep 2020 02:16:15

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:55', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e648112d-7d2c-4e72-9bea-252d480f826b'	System	13 Sep 2020 02:16:15
User entered 'None (0)'	System	13 Sep 2020 02:16:15

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:15:57', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e648112d-7d2c-4e72-9bea-252d480f826b'	System	13 Sep 2020 02:16:15
User entered 'None (0)'	System	13 Sep 2020 02:16:15

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:16:01', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e648112d-7d2c-4e72-9bea-252d480f826b'	System	13 Sep 2020 02:16:15
User entered 'None (0)'	System	13 Sep 2020 02:16:15

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:16:04', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e648112d-7d2c-4e72-9bea-252d480f826b'	System	13 Sep 2020 02:16:15
User entered 'None (0)'	System	13 Sep 2020 02:16:15

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:16:07', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e648112d-7d2c-4e72-9bea-252d480f826b'	System	13 Sep 2020 02:16:15
User entered 'None (0)'	System	13 Sep 2020 02:16:15

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-12T22:16:11', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e648112d-7d2c-4e72-9bea-252d480f826b'	System	13 Sep 2020 02:16:15
User entered 'No (N)'	System	13 Sep 2020 02:16:15

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-12T22:16:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e648112d-7d2c-4e72-9bea-252d480f826b'	System	13 Sep 2020 02:16:15
User entered '12 Sep 2020 22:16'	System	13 Sep 2020 02:16:15

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 4'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:24', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '638b1345-2dab-4b3f-9594-ce0d93f52eed'	System	14 Sep 2020 02:41:47
User entered 'None (0)'	System	14 Sep 2020 02:41:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:28', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '638b1345-2dab-4b3f-9594-ce0d93f52eed'	System	14 Sep 2020 02:41:47
User entered 'None (0)'	System	14 Sep 2020 02:41:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:31', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '638b1345-2dab-4b3f-9594-ce0d93f52eed'	System	14 Sep 2020 02:41:47
User entered 'None (0)'	System	14 Sep 2020 02:41:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:33', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '638b1345-2dab-4b3f-9594-ce0d93f52eed'	System	14 Sep 2020 02:41:47
User entered 'None (0)'	System	14 Sep 2020 02:41:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:36', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '638b1345-2dab-4b3f-9594-ce0d93f52eed'	System	14 Sep 2020 02:41:47
User entered 'None (0)'	System	14 Sep 2020 02:41:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:38', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '638b1345-2dab-4b3f-9594-ce0d93f52eed'	System	14 Sep 2020 02:41:47
User entered 'None (0)'	System	14 Sep 2020 02:41:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-13T22:41:41', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '638b1345-2dab-4b3f-9594-ce0d93f52eed'	System	14 Sep 2020 02:41:47
User entered 'No (N)'	System	14 Sep 2020 02:41:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-13T22:41:44', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '638b1345-2dab-4b3f-9594-ce0d93f52eed'	System	14 Sep 2020 02:41:47
User entered '13 Sep 2020 22:41'	System	14 Sep 2020 02:41:47

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 5'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:38:59', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f3fb58d-2406-4553-ba5a-e0046cc591dd'	System	15 Sep 2020 13:41:28
User entered 'None (0)'	System	15 Sep 2020 13:41:28

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:39:01', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f3fb58d-2406-4553-ba5a-e0046cc591dd'	System	15 Sep 2020 13:41:28
User entered 'None (0)'	System	15 Sep 2020 13:41:28

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:39:03', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f3fb58d-2406-4553-ba5a-e0046cc591dd'	System	15 Sep 2020 13:41:28
User entered 'None (0)'	System	15 Sep 2020 13:41:28

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:39:05', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f3fb58d-2406-4553-ba5a-e0046cc591dd'	System	15 Sep 2020 13:41:28
User entered 'None (0)'	System	15 Sep 2020 13:41:28

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:39:08', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f3fb58d-2406-4553-ba5a-e0046cc591dd'	System	15 Sep 2020 13:41:28
User entered 'None (0)'	System	15 Sep 2020 13:41:28

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:39:10', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f3fb58d-2406-4553-ba5a-e0046cc591dd'	System	15 Sep 2020 13:41:28
User entered 'None (0)'	System	15 Sep 2020 13:41:28

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-15T09:39:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f3fb58d-2406-4553-ba5a-e0046cc591dd'	System	15 Sep 2020 13:41:28
User entered 'No (N)'	System	15 Sep 2020 13:41:28

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T09:41:25', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0f3fb58d-2406-4553-ba5a-e0046cc591dd'	System	15 Sep 2020 13:41:28
User entered '15 Sep 2020 09:41'	System	15 Sep 2020 13:41:28

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 6'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:18', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8f639af-9675-48aa-9930-a6f7a1ef8d1b'	System	16 Sep 2020 01:30:56
User entered 'None (0)'	System	16 Sep 2020 01:30:56

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:21', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8f639af-9675-48aa-9930-a6f7a1ef8d1b'	System	16 Sep 2020 01:30:56
User entered 'None (0)'	System	16 Sep 2020 01:30:56

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:24', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8f639af-9675-48aa-9930-a6f7a1ef8d1b'	System	16 Sep 2020 01:30:56
User entered 'None (0)'	System	16 Sep 2020 01:30:56

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:26', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8f639af-9675-48aa-9930-a6f7a1ef8d1b'	System	16 Sep 2020 01:30:56
User entered 'None (0)'	System	16 Sep 2020 01:30:56

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:28', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8f639af-9675-48aa-9930-a6f7a1ef8d1b'	System	16 Sep 2020 01:30:56
User entered 'None (0)'	System	16 Sep 2020 01:30:56

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:31', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8f639af-9675-48aa-9930-a6f7a1ef8d1b'	System	16 Sep 2020 01:30:56
User entered 'None (0)'	System	16 Sep 2020 01:30:56

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-15T21:30:41', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8f639af-9675-48aa-9930-a6f7a1ef8d1b'	System	16 Sep 2020 01:30:56
User entered 'No (N)'	System	16 Sep 2020 01:30:56

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-15T21:30:44', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'd8f639af-9675-48aa-9930-a6f7a1ef8d1b'	System	16 Sep 2020 01:30:56
User entered '15 Sep 2020 21:30'	System	16 Sep 2020 01:30:56

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:43:17
User entered 'Day 7'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:39:03', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a79ba71-cdfc-43c4-8802-5bff080be75e'	System	17 Sep 2020 00:39:24
User entered 'None (0)'	System	17 Sep 2020 00:39:24

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:39:06', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a79ba71-cdfc-43c4-8802-5bff080be75e'	System	17 Sep 2020 00:39:24
User entered 'None (0)'	System	17 Sep 2020 00:39:24

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:39:08', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a79ba71-cdfc-43c4-8802-5bff080be75e'	System	17 Sep 2020 00:39:24
User entered 'None (0)'	System	17 Sep 2020 00:39:24

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:39:12', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a79ba71-cdfc-43c4-8802-5bff080be75e'	System	17 Sep 2020 00:39:24
User entered 'None (0)'	System	17 Sep 2020 00:39:24

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:39:15', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a79ba71-cdfc-43c4-8802-5bff080be75e'	System	17 Sep 2020 00:39:24
User entered 'None (0)'	System	17 Sep 2020 00:39:24

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:39:18', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a79ba71-cdfc-43c4-8802-5bff080be75e'	System	17 Sep 2020 00:39:24
User entered 'None (0)'	System	17 Sep 2020 00:39:24

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-09-16T20:39:22', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a79ba71-cdfc-43c4-8802-5bff080be75e'	System	17 Sep 2020 00:39:24
User entered 'No (N)'	System	17 Sep 2020 00:39:24

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-09-16T20:39:24', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '5a79ba71-cdfc-43c4-8802-5bff080be75e'	System	17 Sep 2020 00:39:24
User entered '16 Sep 2020 20:39'	System	17 Sep 2020 00:39:24

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:43:17

US3372060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:43:17

US3372060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	21 Sep 2020 17:47:12

US3372060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 07:23:55
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	Alexandra Arango (b) (4)	21 Sep 2020 17:47:21
answered with 'Phone visit was completed within window per protocol.' (Site from System).	(b) (4)	
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Sep 2020 17:47:12
User entered '11 Sep 2020'	Alexandra Arango (b) (4)	21 Sep 2020 17:47:12
	(b) (4)	

US3372060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	21 Sep 2020 17:47:12

US3372060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	21 Sep 2020 17:47:12

US3372060

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	21 Sep 2020 17:48:22

US3372060

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:48:22

US3372060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	21 Sep 2020 17:51:35

US3372060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

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)	22 Sep 2020 05:42:54
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.'	Alexandra Arango (b) (4)	21 Sep 2020 17:52:35
answered with 'Phone visit was completed within window per protocol.' (Site from System).	(b) (4)	
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	21 Sep 2020 17:51:35
User entered '18 Sep 2020'	Alexandra Arango (b) (4)	21 Sep 2020 17:51:35
	(b) (4)	

US3372060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	21 Sep 2020 17:51:35

US3372060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	21 Sep 2020 17:51:35

US3372060

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	21 Sep 2020 17:52:41

US3372060

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:52:41

US3372060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	28 Sep 2020 13:06:40

US3372060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 11:36:20
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	Alexandra Arango (b) (4)	28 Sep 2020 13:07:34
answered with 'Phone visit completed within window per protocol' (Site from System).	(b) (4)	
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Sep 2020 13:06:40
User entered '26 Sep 2020'	Alexandra Arango (b) (4)	28 Sep 2020 13:06:40
	(b) (4)	

US3372060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	28 Sep 2020 13:06:40

US3372060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	28 Sep 2020 13:06:40

US3372060

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	28 Sep 2020 13:07:38

US3372060

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 13:07:38

US3372060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 13:56:01

US3372060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 10:43:24
User entered '02 Oct 2020' reason for change: Data Entry Error	Peter Jacob (b) (4)	06 Oct 2020 23:02:34
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.'	Peter Jacob (b) (4)	06 Oct 2020 23:02:10
answered with 'data correct as is' (Site from System).	(b) (4)	
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	02 Oct 2020 13:56:01
User entered '2 Oct 2020'	Elena Acosta (b) (4)	02 Oct 2020 13:56:01
	(b) (4)	

US3372060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 13:56:01

US3372060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	02 Oct 2020 13:56:01

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 20:12:07

US3372060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:00

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:15

US3372060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:15

US3372060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:23

US3372060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:23

US3372060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '10:16'	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:23

US3372060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '02 Oct 2020 10:16'	System	05 Oct 2020 20:12:23

US3372060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 20:12:27

US3372060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 20:12:27

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 64'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-10-07T15:20:37', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '4319b4b5-4518-4b7d-b2f2-3d5d1ce7a637'	System	07 Oct 2020 19:20:53
User entered 'No (N)'	System	07 Oct 2020 19:20:53

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2020-10-07T15:20:45', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '4319b4b5-4518-4b7d-b2f2-3d5d1ce7a637'	System	07 Oct 2020 19:20:53
User entered 'No (N)'	System	07 Oct 2020 19:20:53

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-10-07T15:20:49', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '4319b4b5-4518-4b7d-b2f2-3d5d1ce7a637'	System	07 Oct 2020 19:20:53
User entered '07 Oct 2020 15:20:49'	System	07 Oct 2020 19:20:53

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 71'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[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 (cee7959f773b7871)', Time: '2020-10-16T16:14:34', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '3a9b9bfe-2bee-434a-b662-64a888cede71'	System	16 Oct 2020 20:14:55
User entered 'No (N)'	System	16 Oct 2020 20:14:55

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2020-10-16T16:14:44', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '3a9b9bfe-2bee-434a-b662-64a888cede71'	System	16 Oct 2020 20:14:55
User entered 'No (N)'	System	16 Oct 2020 20:14:55

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-10-16T16:14:52', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '3a9b9bfe-2bee-434a-b662-64a888cede71'	System	16 Oct 2020 20:14:55
User entered '16 Oct 2020 16:14:52'	System	16 Oct 2020 20:14:55

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 78'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[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 (cee7959f773b7871)', Time: '2020-10-23T09:19:10', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e95081ab-0518-443b-988a-5b532b3d91e6'	System	23 Oct 2020 13:19:23
User entered 'No (N)'	System	23 Oct 2020 13:19:23

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2020-10-23T09:19:13', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e95081ab-0518-443b-988a-5b532b3d91e6'	System	23 Oct 2020 13:19:23
User entered 'No (N)'	System	23 Oct 2020 13:19:23

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-10-23T09:19:16', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: 'e95081ab-0518-443b-988a-5b532b3d91e6'	System	23 Oct 2020 13:19:23
User entered '23 Oct 2020 09:19:16'	System	23 Oct 2020 13:19:23

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 92'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-11-05T19:58:40', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '56dfc630-cfa8-4620-b13a-761b77f0af8b'	System	06 Nov 2020 00:58:57
User entered 'No (N)'	System	06 Nov 2020 00:58:57

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2020-11-05T19:58:49', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '56dfc630-cfa8-4620-b13a-761b77f0af8b'	System	06 Nov 2020 00:58:57
User entered 'No (N)'	System	06 Nov 2020 00:58:57

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-11-05T19:58:53', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '56dfc630-cfa8-4620-b13a-761b77f0af8b'	System	06 Nov 2020 00:58:57
User entered '05 Nov 2020 19:58:53'	System	06 Nov 2020 00:58:57

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered 'Day 99'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

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 (cee7959f773b7871)', Time: '2020-11-15T22:17:06', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0e4a1813-d8e3-4351-9c01-40fd5efffe8e'	System	16 Nov 2020 03:17:22
User entered 'No (N)'	System	16 Nov 2020 03:17:22

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2020-11-15T22:17:14', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0e4a1813-d8e3-4351-9c01-40fd5efffe8e'	System	16 Nov 2020 03:17:22
User entered 'No (N)'	System	16 Nov 2020 03:17:22

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-11-15T22:17:18', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '0e4a1813-d8e3-4351-9c01-40fd5efffe8e'	System	16 Nov 2020 03:17:22
User entered '15 Nov 2020 22:17:18'	System	16 Nov 2020 03:17:22

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 16:31:32

US3372060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 16:31:32
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 16:31:32

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '04 Oct 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '08 Oct 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '11 Oct 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '15 Oct 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '18 Oct 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '22 Oct 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '25 Oct 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '29 Oct 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '01 Nov 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '05 Nov 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '08 Nov 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '12 Nov 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[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 (cee7959f773b7871)', Time: '2020-11-23T17:57:42', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '6b32fdab-90e5-4cd4-ab6d-b0bbf51dff30'	System	23 Nov 2020 22:57:52
User entered 'No (N)'	System	23 Nov 2020 22:57:52

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Have you been exposed to someone with 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 (cee7959f773b7871)', Time: '2020-11-23T17:57:47', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '6b32fdab-90e5-4cd4-ab6d-b0bbf51dff30'	System	23 Nov 2020 22:57:52
User entered 'No (N)'	System	23 Nov 2020 22:57:52

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cee7959f773b7871)', Time: '2020-11-23T17:57:49', User OID: 'PatientReportedOutcome (US3372060)', ODM File OID: '6b32fdab-90e5-4cd4-ab6d-b0bbf51dff30'	System	23 Nov 2020 22:57:52
User entered '23 Nov 2020 17:57:49'	System	23 Nov 2020 22:57:52

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 15:37:12

US3372060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:37:12
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 15:37:12

US3372060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	05 Nov 2020 15:20:24
	(b) (4)	
	(b) (4)	

US3372060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '5 Nov 2020'	Danielle Theodore (b) (4)	05 Nov 2020 15:20:24
	(b) (4)	
	(b) (4)	

US3372060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Danielle Theodore (b) (4)	05 Nov 2020 15:20:24
	(b) (4)	
	(b) (4)	

US3372060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Danielle Theodore (b) (4)	05 Nov 2020 15:20:24
	(b) (4)	
	(b) (4)	

US3372060

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	05 Nov 2020 15:20:31
	(b) (4)	
	(b) (4)	

US3372060

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 15:20:31

US3372060

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:02:00

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:26:52
User entered 'Yes (Y)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 18:57:17

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:29:30
User entered 'USA-US056-2020-mRNA-1273-P301000004'	System	05 Oct 2020 12:29:26
User entered 'New'	(b) (4), (b) (6)	05 Oct 2020 12:29:26

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Joint injury, LLT: Hip injury - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 05:09:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	03 Oct 2020 05:09:53
Data point term sent to Coder	System	02 Oct 2020 19:06:40
User entered 'Right hip trauma'	Elena Acosta (b) (4)	02 Oct 2020 19:06:38
	(b) (4)	

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '14 Aug 2020'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '16 Aug 2020'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	02 Oct 2020 19:08:37
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	02 Oct 2020 19:06:38
User entered 'Yes (Y)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		02 Oct 2020 19:08:37
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		02 Oct 2020 19:08:37
User entered '1' reason for change: Data Entry Error	Elena Acosta (b) (4)	02 Oct 2020 19:08:37
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	02 Oct 2020 19:06:38
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '14 Aug 2020'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '16 Aug 2020'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'Not Related (NOT RELATED)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 19:59:05
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' answered with 'AE is not related to study procedure.' (Site from DM).	Jennifer Torres (b) (4)	18 Nov 2020 17:13:08
DataPoint Un-verified.	Jennifer Torres (b) (4)	18 Nov 2020 17:13:02
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Torres (b) (4)	18 Nov 2020 17:13:02
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 07:05:01
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'Not Applicable (NOT APPLICABLE)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'Not Applicable (NOT APPLICABLE)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:26:04
User closed query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 14:43:33
Query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'updated' (Site from DM).	Mary Sergalis (b) (4)	06 Nov 2020 16:49:28
User entered '0' reason for change: Data Entry Error	Mary Sergalis (b) (4)	06 Nov 2020 16:49:05
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 16:33:43
User opened query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 09:44:27
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '1'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:26:07
DataPoint Un-verified.	Mary Sergalis (b) (4)	06 Nov 2020 16:49:05
User entered '1' reason for change: Data Entry Error	Mary Sergalis (b) (4)	06 Nov 2020 16:49:05
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '0'	Elena Acosta (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide results for CAT scan of the abdomen, CAT scan of the cervical spine, and x-ray of right knee (all on 14 Aug 2020).' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 20:51:29
User closed query 'PV Query: Please confirm the start date for CYCLOBENZAPRINE as it was after right knee injury was considered resolved.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 20:51:18
Query 'PV Query: Please provide results for CAT scan of the abdomen, CAT scan of the cervical spine, and x-ray of right knee (all on 14 Aug 2020).' answered with 'CAT scan abdomen: No evidence of acute traumatic injury., CAT scan cervical spine: Normal with no acute traumatic injuries, Right Knee x-ray: No evidence of acute osseous injury' (Site from Safety).	Mary Sergalis (b) (4)	09 Nov 2020 15:40:19
Query 'PV Query: Please confirm the start date for CYCLOBENZAPRINE as it was after right knee injury was considered resolved.' answered with 'AE /concomitant medication updated ' (Site from Safety).	Mary Sergalis (b) (4)	09 Nov 2020 15:17:11
User opened query 'PV Query: Please provide results for CAT scan of the abdomen, CAT scan of the cervical spine, and x-ray of right knee (all on 14 Aug 2020).' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 20:03:37
User opened query 'PV Query: Please confirm the start date for CYCLOBENZAPRINE as it was after right knee injury was considered resolved.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 20:03:09
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Oct 2020 19:08:37
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	02 Oct 2020 19:08:37
User entered 'After a bicycle-motor vehicle accident went to Delray Medical Center from 08/14/2020 to 08/16/2020 with Right Hip and Right Knee Trauma' reason for change: Data Entry Error	Elena Acosta (b) (4)	02 Oct 2020 19:08:37

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Oct 2020 19:06:38
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 19:06:38

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:29:55
User entered	(b) (4), (b) (6)	05 Oct 2020 12:29:51
'USA-US056-2020-mRNA-1273-P301000004'		

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:43:58
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Joint injury, LLT: Knee injury - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 05:09:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	03 Oct 2020 05:09:53
Data point term sent to Coder	System	02 Oct 2020 19:13:52
User entered 'Right knee trauma'	Elena Acosta (b) (4)	02 Oct 2020 19:13:05
	(b) (4)	

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:44:00
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:44:03
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:44:07
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:44:10
User entered '14 Aug 2020'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:44:12
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:45:12
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:45:14
User entered '04 Sep 2020'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:45:16
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:12:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:45:27
User entered 'Yes (Y)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:45:30
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:45:32
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:45:34
User entered '1'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:45:37
User entered '14 Aug 2020'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:45:39
User closed query 'PV Query: Please confirm hospital discharge date for the event of right knee trauma. Per the narrative, the subject was discharged from the hospital on 16 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:03:12
Query 'PV Query: Please confirm hospital discharge date for the event of right knee trauma. Per the narrative, the subject was discharged from the hospital on 16 Aug 2020.' answered with 'updated' (Site from Safety).	Mary Sergalis (b) (4)	19 Oct 2020 14:41:29
User entered '16 Aug 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	19 Oct 2020 14:41:14
User opened query 'PV Query: Please confirm hospital discharge date for the event of right knee trauma. Per the narrative, the subject was discharged from the hospital on 16 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:51:37
User entered '4 Sep 2020'	Elena Acosta (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:45:43
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:46:27
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:46:19
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:46:21
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:46:23
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:46:24
User entered 'Not Related (NOT RELATED)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:46:18
User entered 'Not Applicable (NOT APPLICABLE)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:46:16
User entered 'Not Applicable (NOT APPLICABLE)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:46:07
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:46:10
User entered '1'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:46:03
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:46:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:45:59
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:45:58
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:03:19
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'No relevant laboratory. Diagnostic Test added' (Site from Safety).	Mary Sergalis (b) (4)	19 Oct 2020 17:32:38
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:51:48
User entered 'After a bicycle-motor vehicle accident went to Delray Medical Center from 08/14/2020 to 08/16/2020 with Right Hip and Right Knee Trauma'	Elena Acosta (b) (4)	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 19:13:05

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:19:55
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\23.0.	Coder Import (b) (4)	09 Nov 2020 15:16:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Nov 2020 15:16:38
Data point term sent to Coder	System	09 Nov 2020 15:15:50
User entered 'Right Knee Pain'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[None](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mary Sergalis (b) (4) [REDACTED] [REDACTED]	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 15:15:36

US3372060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 15:15:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:02:00

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:47:07
User closed query 'Per CDM-Were any prior/concomitant medications and/or vaccinations taken? Is given as 'Yes', however, no medication has been recorded in the 'Prior/Concomitant Medication and Vaccination' form. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 18:14:40
Query 'Per CDM-Were any prior/concomitant medications and/or vaccinations taken? Is given as 'Yes', however, no medication has been recorded in the 'Prior/Concomitant Medication and Vaccination' form. Kindly review and update else clarify.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:03:25
User opened query 'Per CDM-Were any prior/concomitant medications and/or vaccinations taken? Is given as 'Yes', however, no medication has been recorded in the 'Prior/Concomitant Medication and Vaccination' form. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 09:49:21
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 22:26:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 22:26:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 22:26:39
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 22:26:36
User entered empty.	Peter Jacob (b) (4) (b) (4)	11 Aug 2020 22:26:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:07:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:07:34
Data point term sent to Coder	System	26 Aug 2020 19:00:09
User entered 'ambien'	Peter Jacob (b) (4)	26 Aug 2020 18:59:24
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:07:10
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:56:47
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:16:53
User entered 'insomnia'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 18:59:24

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 01:18:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 01:18:15
Data point term sent to Coder	System	06 Oct 2020 16:58:00
Coding entries removed.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:57:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 11:52:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 11:52:29
Data point term sent to Coder	System	26 Aug 2020 19:00:12
User entered 'trazodone'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 10:56:04
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:57:09
User entered 'bilateral knee pain' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:57:06
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:17:18
User entered 'pain knees neck lower back'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 19:00:06

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:59:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:59:20
Data point term sent to Coder Coding entries removed.	System Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:58:00 06 Oct 2020 16:57:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:07:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:07:40
Data point term sent to Coder User entered 'oxycontin'	System Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:14 26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'bilateral knee pain' reason for change:	Peter Jacob (b) (4)	06 Oct 2020 16:57:26
Data Entry Error	(b) (4)	
User entered 'pain knees neck lower back'	Peter Jacob (b) (4)	26 Aug 2020 19:00:29
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '15'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 19:00:29

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

[Name of Medication](#)

Audit	User	Time (GMT)
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)	06 Oct 2020 16:59:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 16:59:20
Data point term sent to Coder Coding entries removed.	System Peter Jacob (b) (4)	06 Oct 2020 16:58:01 06 Oct 2020 16:57:41
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)	27 Aug 2020 18:07:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:07:40
Data point term sent to Coder User entered 'aspirin'	System Peter Jacob (b) (4)	26 Aug 2020 19:01:16 26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 10:56:21
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4)	06 Oct 2020 16:57:45
User entered 'cardiac prophylaxis' reason for change: Data Entry Error	Peter Jacob (b) (4)	06 Oct 2020 16:57:41
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:17:46
User entered 'prophylactic'	Peter Jacob (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 19:01:00

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:07:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:07:47
Data point term sent to Coder	System	26 Aug 2020 19:02:18
User entered 'influenza vaccine'	Peter Jacob (b) (4)	26 Aug 2020 19:01:42
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'influenza prophylaxis/prevention'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.25'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'un Sep 2019'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un Sep 2019'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 19:01:42

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 01:18:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 01:18:15
Data point term sent to Coder	System	06 Oct 2020 16:59:02
User entered 'trazadone'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4) (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'lower back pain'	Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4)	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Peter Jacob (b) (4)	26 Aug 2020 19:02:17
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:58:12
DataPoint activated with code reason code Data required.	Peter Jacob (b) (4)	06 Oct 2020 16:56:41
DataPoint inactivated with code reason code Data not required.	Peter Jacob (b) (4)	26 Aug 2020 19:02:17

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:00:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:00:22
Data point term sent to Coder Coding entries removed.	System Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:03 06 Oct 2020 16:58:48
Coding entries removed.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:58:48
User entered 'oxycontin' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:58:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:56:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:56:49
Data point term sent to Coder User entered 'Doxycycline'	System Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:15:55 02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Peter Jacob (b) (4)	06 Oct 2020 16:58:48
User entered 'Yes (Y)'	Elena Acosta (b) (4)	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'lower back pain' reason for change:	Peter Jacob (b) (4)	06 Oct 2020 16:58:48
Data Entry Error	(b) (4)	
User entered 'Right Knee Trauma laceration Infection Prevention'	Elena Acosta (b) (4)	02 Oct 2020 19:15:09
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '15' reason for change: Data Entry Error	Peter Jacob (b) (4)	06 Oct 2020 16:58:48
User entered '100'	Elena Acosta (b) (4)	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)' reason for change:	Peter Jacob (b) (4)	06 Oct 2020 16:58:48
Data Entry Error	(b) (4)	
User entered 'twice daily (BID)'	Elena Acosta (b) (4)	02 Oct 2020 19:15:09
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2018' reason for change:	Peter Jacob (b) (4)	06 Oct 2020 16:58:48
Data Entry Error	(b) (4)	
User entered '16 Aug 2020'	Elena Acosta (b) (4)	02 Oct 2020 19:15:09
	(b) (4)	

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Peter Jacob (b) (4)	06 Oct 2020 16:58:48
User entered 'No (N)'	Elena Acosta (b) (4)	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	06 Oct 2020 16:58:48
User entered '26 Aug 2020'	Elena Acosta (b) (4)	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:58:48
User entered '2'	System	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 19:15:09

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:24
User closed query 'Please verify if the following medications noted in the hospital records should be added: pancrelipase, oxycodone, doxycycline IV, zolpidem and senna.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:03:22
Query 'Please verify if the following medications noted in the hospital records should be added: pancrelipase, oxycodone, doxycycline IV, zolpidem and senna.' answered with 'ANTIBIOTIC. TAKING ONLY FOR DAYS AS RECORDED.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 13:47:24
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:18
User opened query 'Please verify if the following medications noted in the hospital records should be added: pancrelipase, oxycodone, doxycycline IV, zolpidem and senna.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:28:14
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:19:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:01:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:01:15
Data point term sent to Coder	System	06 Oct 2020 17:00:05
User entered 'doxycycline'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:19:30
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:19:32
User entered 'right knee trauma laceration infection prevention'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:19:34
User entered '100'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:19:37
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:19:38
User entered empty.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:19:45
User entered 'twice daily (BID)'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:19:43
User entered empty.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:19:41
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:19:50
User entered empty.	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:19:48
User entered '16 Aug 2020'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:20:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:19:59
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:19:57
User entered '26 Aug 2020'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:19:53
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 16:59:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 03:30:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 03:30:52
Data point term sent to Coder	System	09 Nov 2020 15:16:53
Coding entries removed.	Mary Sergalis (b) (4) (b) (4)	09 Nov 2020 15:16:07
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	03 Nov 2020 18:37:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:33:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:33:33
Data point term sent to Coder	System	19 Oct 2020 17:32:24
User entered 'Cyclobenzaprine'	Mary Sergalis (b) (4) (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:08:27
User entered 'No (N)'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:08:30
User closed query 'Per CDM: Indication of this Medication is "Right Knee Trauma" and has a start date of "17Oct2020", however the AE for Right Knee Truma has an end date of 04Sep2020. Please review and clarify or update accordingly. ' (Site from DM). User entered 'RIGHT KNEE Pain' reason for change: Data Entry Error	(b) (4), (b) (6) Mary Sergalis (b) (4)	09 Nov 2020 16:06:50 09 Nov 2020 15:16:07
Query 'Per CDM: Indication of this Medication is "Right Knee Trauma" and has a start date of "17Oct2020", however the AE for Right Knee Truma has an end date of 04Sep2020. Please review and clarify or update accordingly. ' answered with 'RIGHT KNEE TRAUMA HAS START DATE OF 14 AUG 2020, WITH THE END DATE OF 04 SEPT 2020 AS RECORDED.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 13:51:05
User opened query 'Per CDM: Indication of this Medication is "Right Knee Trauma" and has a start date of "17Oct2020", however the AE for Right Knee Truma has an end date of 04Sep2020. Please review and clarify or update accordingly. ' (Site from DM). User entered 'Right Knee Trauma'	(b) (4), (b) (6) Mary Sergalis (b) (4)	29 Oct 2020 14:40:10 19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:08:31
User entered '10'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:08:33
User entered 'mg (mg)'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:08:35
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:08:37
User entered 'once daily (QD)'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:08:42
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:08:44
User entered 'Oral (ORAL)'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:08:47
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:07:51
User closed query 'Please verify, noted in esource as 17Aug2020 and continuing.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:07:32
Query 'Please verify, noted in esource as 17Aug2020 and continuing.' answered with 'updated' (Site from CRA).	Mary Sergalis (b) (4)	10 Nov 2020 15:39:19
User entered '17 Aug 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	10 Nov 2020 15:39:03
User opened query 'Please verify, noted in esource as 17Aug2020 and continuing.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 21:30:02
User entered '14 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 13:51:18
User entered '17 Oct 2020'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:10:27
User entered '0'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:51:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	10 Nov 2020 20:48:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 13:51:18
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:51:19
User closed query 'Please verify, noted in source as continuing.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:51:16
Query 'Please verify, noted in source as continuing.' answered with 'corrected' (Site from CRA).	Mary Sergalis (b) (4)	10 Nov 2020 20:48:51
User entered empty; reason for change Data Entry Error	Mary Sergalis (b) (4)	10 Nov 2020 20:48:41
User opened query 'Please verify, noted in source as continuing.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:08:11
User entered '17 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 13:51:18
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:10:07
User entered 'No (N)'	Mary Sergalis (b) (4)	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 17:31:53

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DIGESTIVES, INCL. ENZYMES, ATC: DIGESTIVES, INCL. ENZYMES, ATC: ENZYME PREPARATIONS, PRODUCT: PANCRELIPASE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 07:04:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 07:04:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:51:35
Data point term sent to Coder	System	10 Nov 2020 17:16:30
User entered 'Pancrelipase'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:51:38
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:51:41
User entered 'Pancreatic Enzyme Replacement'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:51:43
User entered '36000'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:51:46
User entered 'IU (IU)'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:51:51
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:51:54
User entered 'twice daily (BID)'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:51:57
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:52:00
User entered 'Oral (ORAL)'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:52:02
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:52:10
User entered '15 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:52:08
User entered '0'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:52:14
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:52:15
User entered '16 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:52:17
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 17:16:02
DataPoint activated with code reason code Data required.	Mary Sergalis (b) (4)	10 Nov 2020 17:13:48
DataPoint inactivated with code reason code Data not required.	Mary Sergalis (b) (4)	09 Nov 2020 15:16:25

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:14:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:14:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:52:55
Data point term sent to Coder	System	10 Nov 2020 17:17:31
User entered 'Morphine'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:52:57
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:52:59
User entered 'Right Knee Pain'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:53:01
User entered '2'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:53:04
User entered 'mg (mg)'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:53:06
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:53:07
User entered 'once (ONCE)'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:53:09
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:53:12
User entered 'Intravenous (INTRAVENOUS)'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:53:13
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:53:16
User entered '15 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:53:18
User entered '0'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:53:20
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:53:22
User entered '15 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:53:24
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:17:10

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:17:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:17:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:55:08
Data point term sent to Coder	System	10 Nov 2020 17:19:44
User entered 'Percocet 5/325'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:55:10
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:55:16
User entered 'Right Knee Pain'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:55:19
User entered '1'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:55:22
User entered 'tablet (TABLET)'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:55:23
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:55:25
User entered 'once (ONCE)'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:55:27
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:55:29
User entered 'Oral (ORAL)'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:55:32
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:55:34
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:55:35
User entered '0'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:55:38
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:55:46
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:55:48
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:19:34

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:56:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:17:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:17:47
Data point term sent to Coder	System	10 Nov 2020 17:21:46
User entered 'Cefazolin'	Mary Sergalis (b) (4) (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:56:08
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:56:10
User entered 'Right Knee Laceration'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:56:13
User entered '1'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:56:16
User entered 'g (g)'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:56:17
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:56:19
User entered 'once (ONCE)'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:56:21
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:56:24
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:56:25
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:56:27
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:56:29
User entered '0'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:56:51
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:56:53
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:56:56
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:20:55

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:54:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:54:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:01:31
Data point term sent to Coder	System	10 Nov 2020 17:23:49
User entered 'Iopamidol'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:01:32
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:01:34
User entered 'Radiopaque Contrast Agent'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:01:35
User entered '1'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:01:40
User entered 'mL (mL)'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:01:44
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:01:43
User entered 'once (ONCE)'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:01:46
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:01:47
User entered 'Intravenous (INTRAVENOUS)'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:01:49
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:01:52
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:01:54
User entered '0'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:01:56
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:01:59
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:00
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:23:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACCELLULAR;TETANUS VACCINE TOXOID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 01:57:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 01:57:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:32
Data point term sent to Coder	System	10 Nov 2020 17:24:50
User entered 'Adacel (Tdap)'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:34
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:35
User entered 'Tetanus Prophylaxis/Prevention'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:37
User entered '0.5'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:38
User entered 'mL (mL)'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:40
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:41
User entered 'once (ONCE)'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:46
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:44
User entered 'Intramuscular (INTRAMUSCULAR)'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:47
User entered empty.	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:49
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:50
User entered '0'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:54
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:53
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:57
User entered 'No (N)'	Mary Sergalis (b) (4)	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:02:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:24:36

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:02:00

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:32:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	19 Oct 2020 17:20:25
User entered 'No (N)'	Peter Jacob (b) (4)	11 Aug 2020 22:26:44

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:02:00

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	19 Oct 2020 17:21:10

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:02:00

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered 'CAT Scan of the Abdomen'	Mary Sergalis (b) (4)	19 Oct 2020 17:21:10

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:02:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered 'Adverse Event (AE)'	Mary Sergalis (b) (4)	19 Oct 2020 17:21:10

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:02:00

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 17:21:10

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:02:00

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	19 Oct 2020 17:22:58

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:02:00

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered 'CAT Scan of the Cervical Spine'	Mary Sergalis (b) (4)	19 Oct 2020 17:22:58

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:02:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered 'Adverse Event (AE)'	Mary Sergalis (b) (4)	19 Oct 2020 17:22:58

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:02:00

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 17:22:58

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:02:00

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered '14 Aug 2020'	Mary Sergalis (b) (4)	19 Oct 2020 17:28:13

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:02:00

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered 'X-Ray of Right Knee'	Mary Sergalis (b) (4)	19 Oct 2020 17:28:13

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:02:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered 'Adverse Event (AE)'	Mary Sergalis (b) (4)	19 Oct 2020 17:28:13

US3372060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:02:00

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:32:50
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 17:28:13

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:44
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'USA-US056-2020-MRNA-1273-P301000004'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:46
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:41
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:33
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Mira'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:32
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Baron'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '2277 Palm beach Lakes Blvd'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:29
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'West Palm Beach'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:27
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '33409'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:25
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:03:30
User entered 'US'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Nov 2020 18:04:12
User entered '4'	System	19 Nov 2020 17:55:37
User entered '3'	System	09 Nov 2020 20:53:10
User entered '2'	System	20 Oct 2020 14:03:40
User entered '1'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:44
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'USA-US056-2020-MRNA-1273-P301000004'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:46
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:41
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:33
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Mira'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:32
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Baron'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '2277 Palm beach Lakes Blvd'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:29
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'West Palm Beach'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:27
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '33409'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:25
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:03:30
User entered 'US'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Nov 2020 18:04:12
User entered '4'	System	19 Nov 2020 17:55:37
User entered '3'	System	09 Nov 2020 20:53:10
User entered '2'	System	20 Oct 2020 14:03:40
User entered '1'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:02:00

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:21
User entered '05/Oct/2020 08:32'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:02:00

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)	27 Oct 2020 18:09:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:03:30
User entered '1' reason for change: New Information	(b) (4), (b) (6)	05 Oct 2020 12:32:06
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 12:31:57

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:44
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'USA-US056-2020-MRNA-1273-P301000004'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:46
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:41
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:33
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Mira'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:32
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Baron'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '2277 Palm beach Lakes Blvd'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:29
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'West Palm Beach'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:27
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '33409'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:25
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:03:30
User entered 'US'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Nov 2020 18:04:12
User entered '4'	System	19 Nov 2020 17:55:37
User entered '3'	System	09 Nov 2020 20:53:10
User entered '2'	System	20 Oct 2020 14:03:40
User entered '1'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:02:00

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:24
User entered '20/Oct/2020 14:03'	System	20 Oct 2020 14:03:40

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:02:00

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:52:48
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:25
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 14:03:40

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:44
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'USA-US056-2020-MRNA-1273-P301000004'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:46
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:41
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:33
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Mira'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:32
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Baron'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '2277 Palm beach Lakes Blvd'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:29
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'West Palm Beach'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:27
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '33409'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:25
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:03:30
User entered 'US'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Nov 2020 18:04:12
User entered '4'	System	19 Nov 2020 17:55:37
User entered '3'	System	09 Nov 2020 20:53:10
User entered '2'	System	20 Oct 2020 14:03:40
User entered '1'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:02:00

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '09/Nov/2020 20:53'	System	09 Nov 2020 20:53:10

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:02:00

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 17:55:18
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 20:53:10

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:44
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'USA-US056-2020-MRNA-1273-P301000004'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:46
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:41
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:33
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Mira'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:32
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Baron'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '2277 Palm beach Lakes Blvd'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:29
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'West Palm Beach'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:27
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '33409'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:25
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:03:30
User entered 'US'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Nov 2020 18:04:12
User entered '4'	System	19 Nov 2020 17:55:37
User entered '3'	System	09 Nov 2020 20:53:10
User entered '2'	System	20 Oct 2020 14:03:40
User entered '1'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:02:00

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '19/Nov/2020 17:55'	System	19 Nov 2020 17:55:37

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:02:00

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:03:59
User entered '1'	(b) (4), (b) (6)	19 Nov 2020 17:55:37

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:44
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'USA-US056-2020-MRNA-1273-P301000004'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:46
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:41
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Yes (Y)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'No (N)'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:33
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Mira'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:32
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'Baron'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '2277 Palm beach Lakes Blvd'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:29
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered 'West Palm Beach'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:27
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:31:53
User entered '33409'	System	05 Oct 2020 12:29:26

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:09:25
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:03:30
User entered 'US'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Nov 2020 18:04:12
User entered '4'	System	19 Nov 2020 17:55:37
User entered '3'	System	09 Nov 2020 20:53:10
User entered '2'	System	20 Oct 2020 14:03:40
User entered '1'	System	05 Oct 2020 12:32:06

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:02:00

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:44:39
User entered '19/Nov/2020 18:04'	System	19 Nov 2020 18:04:12

US3372060

Folder: SAE USA-US056-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:02:00

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)	20 Nov 2020 20:44:41
User entered '1'	(b) (4), (b) (6)	19 Nov 2020 18:04:12