

US3372110 (Prod: Palm Beach Research Center)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:02:58

All time stamps listed in this document are displayed in GMT

US3372110

Form: Participant Creation

Generated On: 26 Nov 2020 11:02:58

[Participant ID](#)

US3372110

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

US3372110

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:58

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	52
Age Units	YEARS
Age (Derived)	52
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

US3372110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:58

Date of Informed Consent (<i>dd MMM yyyy</i>)	13 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

US3372110

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:02:58

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:02:58

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:58

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	24 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3372110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:58

Condition	REMOVAL OF SINUS POLYPS
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)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

US3372110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:58

Condition	CLEFT LIP
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1970
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	JAN 1970
Stop Year (derived)	1970

US3372110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:58

Condition	CLEFT LIP REPAIR
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1970
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	JAN 1970
Stop Year (derived)	1970

US3372110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:58

Condition	SINUS POLYPS
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)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	13 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:06 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 10:06
Height (<i>xxx.x</i>)	183.4 cm
Weight (<i>xxx.x</i>)	117.8 kg
BMI (<i>xxx.x</i>)	35.02246 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)	

US3372110

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

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

LAWYER WORKS IN OFFICE
ENVIRONMENT WITH APPROX
100 OTHER EMPLOYEES

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3372110

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3372110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:58

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 103567

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 ☒

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:58

Height	ND - Not Done
Weight	ND - Not Done

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

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)	13 AUG 2020
Time of assessment (00:00-23:59)	10:06 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 10:06
Temperature (xxx.x)	36.3 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

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)	13 AUG 2020
Time of assessment (00:00-23:59)	12:59 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 12:59
Temperature (xxx.x)	36.6 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3372110

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

US3372110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	13 AUG 2020
What was the treatment time? (00:00-23:59)	11:28 (24 HR)
Treatment Date and Time (derived)	13 AUG 2020 11:28
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

US3372110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:58

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	13 AUG 2020
Collection time (<i>00:00-23:59</i>)	10:51 (24 HR)
Collection date and time (derived)	13 AUG 2020 10:51

US3372110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:02:58

Collection date (<i>dd MMM yyyy</i>)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:51	13 AUG 2020 10:51
Nasopharyngeal Swab 2	No		

US3372110

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 12:17

PC Open Date & Time

13 AUG 2020 11:48

PC Close Date & Time

13 AUG 2020 14:18

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

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 97.4 °F

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

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

PC Time Stamp	13 AUG 2020 15:14
PC Open Date & Time	13 AUG 2020 15:13
PC Close Date & Time	14 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

14 AUG 2020 12:00

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 12:00

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:58

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

16 AUG 2020 12:02

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 12:25

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:58

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

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

18 AUG 2020 12:08

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 12:03

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 12:17

PC Open Date & Time

13 AUG 2020 11:48

PC Close Date & Time

13 AUG 2020 14:18

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 15:14

PC Open Date & Time

13 AUG 2020 15:13

PC Close Date & Time

14 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:58

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

14 AUG 2020 12:01

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 12:01

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 12:02

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 12:25

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 12:08

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 12:03

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 12:18
PC Open Date & Time	13 AUG 2020 11:48
PC Close Date & Time	13 AUG 2020 14:18

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 15:15
PC Open Date & Time	13 AUG 2020 15:13
PC Close Date & Time	14 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:58

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 ☒

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:58

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 ☒

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:58

Yes ☐	
PC Time stamp	15 AUG 2020 12:01
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:58

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 ☒

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:58

Yes ☐	
PC Time stamp	16 AUG 2020 12:02
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:58

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 ☒

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:58

Yes ☐	
PC Time stamp	17 AUG 2020 12:26
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:58

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 ☒

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:58

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 ☒

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:58

Yes ☐	
PC Time stamp	19 AUG 2020 12:03
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3372110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372110

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372110

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372110

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	15 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	15 SEP 2020
Time of assessment (00:00-23:59)	09:16 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 09:16
Temperature (xxx.x)	36.6 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 SEP 2020

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

US3372110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

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? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3372110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:58

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	15 SEP 2020
Collection time (<i>00:00-23:59</i>)	10:04 (24 HR)
Collection date and time (derived)	15 SEP 2020 10:04

US3372110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:02:58

Collection date (<i>dd MMM yyyy</i>)			15 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	10:02	15 SEP 2020 10:02
Nasopharyngeal Swab 2	No		

US3372110

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	08 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3372110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

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)	

US3372110

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:58

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3372110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:58

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	08 OCT 2020
Collection time (<i>00:00-23:59</i>)	11:06 (24 HR)
Collection date and time (derived)	08 OCT 2020 11:06

US3372110

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

15 OCT 2020 12:01:18

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

20 OCT 2020 05:33:20

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 OCT 2020 12:01:15
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 NOV 2020 00:02:35
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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	17 NOV 2020 03:26:15
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

Date and time of submission

24 NOV 2020 02:29:37

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

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13 APR 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

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20 APR 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

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27 APR 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

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01 JUN 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

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15 JUN 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

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20 JUL 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

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27 JUL 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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03 AUG 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

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10 AUG 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

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17 AUG 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

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10 SEP 2022 00:01

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14 SEP 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3372110

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3372110

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:02:58

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3372110

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:02:58

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

AEID	
Adverse event	ACUTE SINUSITIS
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)	4 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	10 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	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)	308 of 1506

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

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) _____	

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

AEID	
Adverse event	SINUS INFECTION
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)	4 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	8 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	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)	310 of 1506

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

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)	

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

AEID	USA-US056-2020-MRNA-1273-P30 1000007
Adverse event	COVID 19
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)	31 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)	14 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	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	312 of 1506

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:02:58

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

Yes ☒

No ☐

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

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

	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	☒

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

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)	24 JUL 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 ☒

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

Name of Medication	TESTOSTERONE INJECTIONS
Prophylaxis	Yes ☐ No ☒
Indication	LOW TESTOSTERONE
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 ☒

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

Name of Medication	SINGULAIR
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC SINUSITIS
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 ☐

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

Name of Medication	AZITHROMYCIN
Prophylaxis	Yes ☐ No ☒
Indication	SINUS INFECTION
Dose per administration	250
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 ☐

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

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)	04 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ☒
If not Ongoing, End date (dd MMM yyyy)	10 SEP 2020
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 ☒

US3372110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:02:58

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3372110

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:02:58

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

US3372110

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:02:58

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 ☐

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

SAEID	USA-US056-2020-MRNA-1273-P301000007
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)	1

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:02:58

SAEID	USA-US056-2020-MRNA-1273-P301000007
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)	1
Date of submission (Pre-filled from custom function)	16/NOV/2020 21:53
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

Audit

US3372110 (Prod: Palm Beach Research Center)

US3372110

Form: Participant Creation

Generated On: 26 Nov 2020 11:02:58

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3372110'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 13:19:52

US3372110

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 15:03:59

US3372110

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 13:19:53

US3372110

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Aug 2020 15:03:59

US3372110

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	13 Aug 2020 15:03:59

US3372110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered (b) (6) 1968'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 13:19:54

US3372110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:58

[Age](#)

Audit	User	Time (GMT)
User entered '52'	(b) (4), (b) (6)	13 Aug 2020 15:04:24

US3372110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:58

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	13 Aug 2020 15:04:24

US3372110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:58

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '52'	System	13 Aug 2020 15:05:01

US3372110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:58

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	(b) (4), (b) (6)	13 Aug 2020 15:04:24

US3372110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:58

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	13 Aug 2020 15:04:24

US3372110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:58

White

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	13 Aug 2020 15:04:24

US3372110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:58

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:04:24

US3372110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:58

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:04:24

US3372110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:58

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:04:24

US3372110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:58

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:04:24

US3372110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:58

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:04:24

US3372110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:58

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:04:24

US3372110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:58

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:04:24

US3372110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:02:58

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:04:24

US3372110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 15:05:01

US3372110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	13 Aug 2020 15:05:01

US3372110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '2020'	System	13 Aug 2020 15:05:01

US3372110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:58

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	13 Aug 2020 15:05:01

US3372110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 15:05:01

US3372110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:05:01

US3372110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:58

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:05:01

US3372110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:58

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:05:01

US3372110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:58

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 13:19:53

US3372110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:02:58

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:06:46

US3372110

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 15:06:46

US3372110

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:02:58

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:14:47

US3372110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:38:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:38:54
Data point term sent to Coder	System	02 Oct 2020 18:37:29
User entered 'hypertension'	Peter Jacob (b) (4)	02 Oct 2020 18:37:20
	(b) (4)	

US3372110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:37:20

US3372110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:37:20

US3372110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:37:20

US3372110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:37:20

US3372110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:37:20

US3372110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	02 Oct 2020 18:37:20

US3372110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '2016'	System	02 Oct 2020 18:37:20

US3372110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:37:20

US3372110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:37:20

US3372110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:41:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:41:47
Data point term sent to Coder	System	02 Oct 2020 18:40:36
User entered 'hypercholesterolemia'	Peter Jacob (b) (4)	02 Oct 2020 18:40:18
	(b) (4)	

US3372110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '24 Jul 2020'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:18

US3372110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:18

US3372110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:18

US3372110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:18

US3372110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:18

US3372110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	02 Oct 2020 18:40:18

US3372110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '2020'	System	02 Oct 2020 18:40:18

US3372110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:40:18

US3372110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:40:18

US3372110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:41:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:41:48
Data point term sent to Coder	System	02 Oct 2020 18:40:37
User entered 'low testosterone'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:35

US3372110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:35

US3372110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:35

US3372110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:35

US3372110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:35

US3372110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:35

US3372110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	02 Oct 2020 18:40:35

US3372110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '2010'	System	02 Oct 2020 18:40:35

US3372110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:40:35

US3372110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:40:35

US3372110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Chronic sinusitis, LLT: Chronic sinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:42:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:42:49
Data point term sent to Coder	System	02 Oct 2020 18:41:38
User entered 'chronic sinusitis'	Peter Jacob (b) (4)	02 Oct 2020 18:40:44
	(b) (4)	

US3372110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:44

US3372110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:44

US3372110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:44

US3372110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:44

US3372110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:44

US3372110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	02 Oct 2020 18:40:44

US3372110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '2010'	System	02 Oct 2020 18:40:44

US3372110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:40:44

US3372110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:40:44

US3372110

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinuplasty, LLT: Balloon sinuplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 10:50:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 10:50:49
Data point term sent to Coder	System	02 Oct 2020 18:46:51
User entered 'sinus ostial dilation'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:46:09

US3372110

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'un UNK 1998'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:46:09

US3372110

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:46:09

US3372110

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:46:09

US3372110

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'un UNK 1998'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:46:09

US3372110

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:46:09

US3372110

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	02 Oct 2020 18:46:09

US3372110

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '1998'	System	02 Oct 2020 18:46:09

US3372110

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	02 Oct 2020 18:46:09

US3372110

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '1998'	System	02 Oct 2020 18:46:09

US3372110

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Sinus polyp, LLT: Sinus polyp - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 05:10:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 05:10:53
Data point term sent to Coder	System	02 Oct 2020 18:47:52
User entered 'removal of sinus polyps'	Peter Jacob (b) (4)	02 Oct 2020 18:47:31

US3372110

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:47:31

US3372110

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:47:31

US3372110

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:47:31

US3372110

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:47:31

US3372110

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:47:31

US3372110

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	02 Oct 2020 18:47:31

US3372110

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '2018'	System	02 Oct 2020 18:47:31

US3372110

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	02 Oct 2020 18:47:31

US3372110

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '2018'	System	02 Oct 2020 18:47:31

US3372110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Musculoskeletal and connective tissue disorders congenital, HLT: Musculoskeletal and connective tissue disorders of face, neck and jaw congenital, PT: Cleft lip, LLT: Cleft lip - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:53:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:53:50
Data point term sent to Coder	System	02 Oct 2020 18:53:11
User entered 'cleft lip'	Peter Jacob (b) (4)	02 Oct 2020 18:53:03
	(b) (4)	

US3372110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'un UNK 1970'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:53:03

US3372110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:53:03

US3372110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:53:03

US3372110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'un UNK 1970'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:53:03

US3372110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:53:03

US3372110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Jan 1970'	System	02 Oct 2020 18:53:03

US3372110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '1970'	System	02 Oct 2020 18:53:03

US3372110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Jan 1970'	System	02 Oct 2020 18:53:03

US3372110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '1970'	System	02 Oct 2020 18:53:03

US3372110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Lip therapeutic procedures, PT: Cleft lip repair, LLT: Cleft lip repair - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:56:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:56:50
Data point term sent to Coder	System	02 Oct 2020 18:56:18
User entered 'cleft lip repair'	Peter Jacob (b) (4)	02 Oct 2020 18:55:20
	(b) (4)	

US3372110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'un UNK 1970'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:55:20

US3372110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:55:20

US3372110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:55:20

US3372110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'un UNK 1970'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:55:20

US3372110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:55:20

US3372110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Jan 1970'	System	02 Oct 2020 18:55:20

US3372110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '1970'	System	02 Oct 2020 18:55:20

US3372110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Jan 1970'	System	02 Oct 2020 18:55:20

US3372110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '1970'	System	02 Oct 2020 18:55:20

US3372110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Sinus polyp, LLT: Sinus polyp - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:56:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:56:50
Data point term sent to Coder	System	02 Oct 2020 18:56:19
User entered 'sinus polyps'	Peter Jacob (b) (4)	02 Oct 2020 18:55:57
	(b) (4)	

US3372110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:55:57

US3372110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:55:57

US3372110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:55:57

US3372110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:55:57

US3372110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:55:57

US3372110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	02 Oct 2020 18:55:57

US3372110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '2018'	System	02 Oct 2020 18:55:57

US3372110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	02 Oct 2020 18:55:57

US3372110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '2018'	System	02 Oct 2020 18:55:57

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '10:06'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 10:06'	System	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '183.4' cm	Peter Jacob (b) (4)	18 Aug 2020 22:33:55
DataPoint set to visible.	(b) (4) System	13 Aug 2020 15:06:46

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '117.8' kg	Peter Jacob (b) (4)	18 Aug 2020 22:33:55
DataPoint set to visible.	(b) (4) System	13 Aug 2020 15:06:46

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '35.02246'	System	16 Sep 2020 23:54:49
User entered '35.0'	System	18 Aug 2020 22:33:55
DataPoint set to visible.	System	13 Aug 2020 15:06:46

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	18 Aug 2020 22:33:55
DataPoint set to visible.	System	13 Aug 2020 15:06:46

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

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 12:16:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 16:02:45
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 16:02:31
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 13:32:57
User entered '36.3' C	Peter Jacob (b) (4)	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 16:02:45
User entered 'Oral (Oral)'	Peter Jacob (b) (4)	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[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 16:02:45
User entered '75'	Peter Jacob (b) (4)	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[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 16:02:45
User entered '16'	Peter Jacob (b) (4)	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[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 16:02:45
User entered '142'	Peter Jacob (b) (4)	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[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 16:02:45
User entered '88'	Peter Jacob (b) (4)	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:34:43

US3372110

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	30 Sep 2020 21:32:09
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	15 Sep 2020 13:48:38
User entered '13 Aug 2020'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:34:43

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

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)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

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)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

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)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

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)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

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)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

[Specify](#)

Audit	User	Time (GMT)
User entered 'Lawyer works in office environment with approx 100 other employees'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

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'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '1'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:02:58

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 15:05:24

US3372110

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 15:05:24

US3372110

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Aug 2020 15:05:24

US3372110

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	13 Aug 2020 15:05:24

US3372110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	13 Aug 2020 14:59:35

US3372110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:58

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:05:41
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:05:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 14:59:35
User entered '103567' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 14:59:35

US3372110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:58

[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]	13 Aug 2020 14:59:35

US3372110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:58

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)	13 Aug 2020 15:06:04

US3372110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:06:04

US3372110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:06:04

US3372110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:58

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:06:04

US3372110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:02:58

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:06:04

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:58

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 12:16:02
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 14:58:27
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 14:58:10
	(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 13:32:49
User entered '183.4' cm	Peter Jacob (b) (4)	18 Aug 2020 22:42:03
	(b) (4)	

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:58

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 14:58:10
User entered '117.8' kg	Peter Jacob (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:58

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 12:16:02
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 14:58:27
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 14:58:10
	(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 13:32:49
User entered '183.4' cm	Peter Jacob (b) (4)	18 Aug 2020 22:42:03
	(b) (4)	

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:58

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 14:58:10
User entered '117.8' kg	Peter Jacob (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '10:06'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 10:06'	System	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.3' C	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '75'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '16'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '142'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '88'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:58

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 12:16:02
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 14:58:27
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 14:58:10
	(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 13:32:49
User entered '183.4' cm	Peter Jacob (b) (4)	18 Aug 2020 22:42:03
	(b) (4)	

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:02:58

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 14:58:10
User entered '117.8' kg	Peter Jacob (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '12:59'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:59'	System	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '77'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '15'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '134'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '90'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:53

US3372110

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:53

US3372110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 15:32:14

US3372110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:32:14

US3372110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:32:14

US3372110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 15:32:14

US3372110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 15:32:14

US3372110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '11:28'	(b) (4), (b) (6)	13 Aug 2020 15:32:14

US3372110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:28'	System	13 Aug 2020 15:32:14

US3372110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	13 Aug 2020 15:32:14

US3372110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	13 Aug 2020 15:32:14

US3372110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 15:32:14

US3372110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:07

US3372110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:07

US3372110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:51'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:07

US3372110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 10:51'	System	18 Aug 2020 22:43:07

US3372110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:02:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:15

US3372110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:02:58

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:15

US3372110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:02:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:15

US3372110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:02:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:51'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:15

US3372110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 10:51'	System	18 Aug 2020 22:43:15

US3372110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:02:58

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:15

US3372110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:02:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:15

US3372110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:02:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:15

US3372110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 22:43:15

US3372110

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:19

US3372110

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 22:43:19

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:10:51', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '09c88ba0-c313-4cc7-9fdd-ac6cec607aeb'	System	13 Aug 2020 16:17:53
User entered 'Yes (Y)'	System	13 Aug 2020 16:17:53

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:11:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '09c88ba0-c313-4cc7-9fdd-ac6cec607aeb'	System	13 Aug 2020 16:17:53
User entered '97.8'	System	13 Aug 2020 16:17:53

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:17:42', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '09c88ba0-c313-4cc7-9fdd-ac6cec607aeb'	System	13 Aug 2020 16:17:53
User entered 'No (N)'	System	13 Aug 2020 16:17:53

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:17:48', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '09c88ba0-c313-4cc7-9fdd-ac6cec607aeb'	System	13 Aug 2020 16:17:53
User entered '13 Aug 2020 12:17'	System	13 Aug 2020 16:17:53

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:48'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 14:18'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:13:43', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '35f603e1-271a-40ec-a2e0-3efa6861a0be'	System	13 Aug 2020 19:14:14
User entered 'Yes (Y)'	System	13 Aug 2020 19:14:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:13:57', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '35f603e1-271a-40ec-a2e0-3efa6861a0be' User entered '97.4'	System	13 Aug 2020 19:14:14
	System	13 Aug 2020 19:14:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:04', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '35f603e1-271a-40ec-a2e0-3efa6861a0be'	System	13 Aug 2020 19:14:14
User entered 'No (N)'	System	13 Aug 2020 19:14:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:09', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '35f603e1-271a-40ec-a2e0-3efa6861a0be' User entered '13 Aug 2020 15:14'	System	13 Aug 2020 19:14:14
	System	13 Aug 2020 19:14:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 15:13'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 2'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:00:28', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '78d11f08-e9f7-4d50-9244-ef5c87443d0d'	System	14 Aug 2020 16:00:50
User entered 'Yes (Y)'	System	14 Aug 2020 16:00:50

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:00:36', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '78d11f08-e9f7-4d50-9244-ef5c87443d0d'	System	14 Aug 2020 16:00:50
User entered '97.5'	System	14 Aug 2020 16:00:50

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:00:40', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '78d11f08-e9f7-4d50-9244-ef5c87443d0d'	System	14 Aug 2020 16:00:50
User entered 'No (N)'	System	14 Aug 2020 16:00:50

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:00:45', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '78d11f08-e9f7-4d50-9244-ef5c87443d0d'	System	14 Aug 2020 16:00:50
User entered '14 Aug 2020 12:00'	System	14 Aug 2020 16:00:50

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 3'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:00:19', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'f7c1e6ec-d248-4fa6-af07-e603adf2d89b'	System	15 Aug 2020 16:00:56
User entered 'Yes (Y)'	System	15 Aug 2020 16:00:56

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:00:35', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'f7c1e6ec-d248-4fa6-af07-e603adf2d89b'	System	15 Aug 2020 16:00:56
User entered '97.4'	System	15 Aug 2020 16:00:56

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:00:39', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'f7c1e6ec-d248-4fa6-af07-e603adf2d89b'	System	15 Aug 2020 16:00:56
User entered 'No (N)'	System	15 Aug 2020 16:00:56

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:00:53', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'f7c1e6ec-d248-4fa6-af07-e603adf2d89b'	System	15 Aug 2020 16:00:56
User entered '15 Aug 2020 12:00'	System	15 Aug 2020 16:00:56

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 4'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:01:53', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a0e538bc-2d7d-40b7-aafe-20a7882f06d7'	System	16 Aug 2020 16:02:11
User entered 'Yes (Y)'	System	16 Aug 2020 16:02:11

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:02', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a0e538bc-2d7d-40b7-aafe-20a7882f06d7'	System	16 Aug 2020 16:02:11
User entered '97.3'	System	16 Aug 2020 16:02:11

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:05', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a0e538bc-2d7d-40b7-aafe-20a7882f06d7'	System	16 Aug 2020 16:02:11
User entered 'No (N)'	System	16 Aug 2020 16:02:11

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:08', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a0e538bc-2d7d-40b7-aafe-20a7882f06d7'	System	16 Aug 2020 16:02:11
User entered '16 Aug 2020 12:02'	System	16 Aug 2020 16:02:11

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 5'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:18', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2cc96e97-ecd9-4b64-b10d-e815f579ad1d'	System	18 Aug 2020 16:08:30
User entered 'Yes (Y)'	System	18 Aug 2020 16:08:30

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:24', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2cc96e97-ecd9-4b64-b10d-e815f579ad1d'	System	18 Aug 2020 16:08:30
User entered '97.4'	System	18 Aug 2020 16:08:30

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:28', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2cc96e97-ecd9-4b64-b10d-e815f579ad1d'	System	18 Aug 2020 16:08:30
User entered 'No (N)'	System	18 Aug 2020 16:08:30

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:31', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2cc96e97-ecd9-4b64-b10d-e815f579ad1d'	System	18 Aug 2020 16:08:30
User entered '17 Aug 2020 12:25'	System	18 Aug 2020 16:08:30

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:58

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 6'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:08:29', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'dcf76ff5-ae49-4d85-a3b0-49e04fc5f934'	System	18 Aug 2020 16:08:44
User entered 'Yes (Y)'	System	18 Aug 2020 16:08:44

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:08:35', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'dcf76ff5-ae49-4d85-a3b0-49e04fc5f934'	System	18 Aug 2020 16:08:44
User entered '97.0'	System	18 Aug 2020 16:08:44

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:08:39', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'dcf76ff5-ae49-4d85-a3b0-49e04fc5f934'	System	18 Aug 2020 16:08:44
User entered 'No (N)'	System	18 Aug 2020 16:08:44

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:08:42', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'dcf76ff5-ae49-4d85-a3b0-49e04fc5f934'	System	18 Aug 2020 16:08:44
User entered '18 Aug 2020 12:08'	System	18 Aug 2020 16:08:44

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 7'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:02:54', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0fb49390-1a09-43d2-b6f4-8741898350cf'	System	19 Aug 2020 16:03:10
User entered 'Yes (Y)'	System	19 Aug 2020 16:03:10

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:02:59', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0fb49390-1a09-43d2-b6f4-8741898350cf'	System	19 Aug 2020 16:03:10
User entered '97.3'	System	19 Aug 2020 16:03:10

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:02', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0fb49390-1a09-43d2-b6f4-8741898350cf'	System	19 Aug 2020 16:03:10
User entered 'No (N)'	System	19 Aug 2020 16:03:10

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:05', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0fb49390-1a09-43d2-b6f4-8741898350cf'	System	19 Aug 2020 16:03:10
User entered '19 Aug 2020 12:03'	System	19 Aug 2020 16:03:10

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:16:12', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a4b56961-eff9-47c6-b1dc-b5e86958ca75'	System	13 Aug 2020 16:17:40
User entered 'None (1)'	System	13 Aug 2020 16:17:40

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:16:15', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a4b56961-eff9-47c6-b1dc-b5e86958ca75'	System	13 Aug 2020 16:17:40
User entered 'No (N)'	System	13 Aug 2020 16:17:40

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:16:18', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a4b56961-eff9-47c6-b1dc-b5e86958ca75'	System	13 Aug 2020 16:17:40
User entered 'No (N)'	System	13 Aug 2020 16:17:40

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:16:21', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a4b56961-eff9-47c6-b1dc-b5e86958ca75'	System	13 Aug 2020 16:17:40
User entered 'None (1)'	System	13 Aug 2020 16:17:40

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:17:33', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a4b56961-eff9-47c6-b1dc-b5e86958ca75'	System	13 Aug 2020 16:17:40
User entered '13 Aug 2020 12:17'	System	13 Aug 2020 16:17:40

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:48'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 14:18'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:26', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3704d3f4-5d5a-4b3c-922a-225fe5b9e256'	System	13 Aug 2020 19:14:47
User entered 'None (1)'	System	13 Aug 2020 19:14:47

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:31', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3704d3f4-5d5a-4b3c-922a-225fe5b9e256'	System	13 Aug 2020 19:14:47
User entered 'No (N)'	System	13 Aug 2020 19:14:47

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:35', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3704d3f4-5d5a-4b3c-922a-225fe5b9e256'	System	13 Aug 2020 19:14:47
User entered 'No (N)'	System	13 Aug 2020 19:14:47

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:39', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3704d3f4-5d5a-4b3c-922a-225fe5b9e256'	System	13 Aug 2020 19:14:47
User entered 'None (1)'	System	13 Aug 2020 19:14:47

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:43', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3704d3f4-5d5a-4b3c-922a-225fe5b9e256'	System	13 Aug 2020 19:14:47
User entered '13 Aug 2020 15:14'	System	13 Aug 2020 19:14:47

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 15:13'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 2'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:00:49', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'ece591e0-2ac0-458d-a7e2-d52cba15d202'	System	14 Aug 2020 16:01:07
User entered 'None (1)'	System	14 Aug 2020 16:01:07

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:00:52', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'ece591e0-2ac0-458d-a7e2-d52cba15d202'	System	14 Aug 2020 16:01:07
User entered 'No (N)'	System	14 Aug 2020 16:01:07

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:00:55', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'ece591e0-2ac0-458d-a7e2-d52cba15d202'	System	14 Aug 2020 16:01:07
User entered 'No (N)'	System	14 Aug 2020 16:01:07

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:00:57', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'ece591e0-2ac0-458d-a7e2-d52cba15d202'	System	14 Aug 2020 16:01:07
User entered 'None (1)'	System	14 Aug 2020 16:01:07

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:01:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'ece591e0-2ac0-458d-a7e2-d52cba15d202'	System	14 Aug 2020 16:01:07
User entered '14 Aug 2020 12:01'	System	14 Aug 2020 16:01:07

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 3'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:00:57', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '28dbea7d-041d-484e-9b5a-959c8c3dc6cf'	System	15 Aug 2020 16:01:14
User entered 'None (1)'	System	15 Aug 2020 16:01:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '28dbea7d-041d-484e-9b5a-959c8c3dc6cf'	System	15 Aug 2020 16:01:14
User entered 'No (N)'	System	15 Aug 2020 16:01:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:02', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '28dbea7d-041d-484e-9b5a-959c8c3dc6cf'	System	15 Aug 2020 16:01:14
User entered 'No (N)'	System	15 Aug 2020 16:01:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:06', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '28dbea7d-041d-484e-9b5a-959c8c3dc6cf'	System	15 Aug 2020 16:01:14
User entered 'None (1)'	System	15 Aug 2020 16:01:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:08', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '28dbea7d-041d-484e-9b5a-959c8c3dc6cf'	System	15 Aug 2020 16:01:14
User entered '15 Aug 2020 12:01'	System	15 Aug 2020 16:01:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 4'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:11', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '13387b13-3c5c-4e43-a515-15c155a6e632'	System	16 Aug 2020 16:02:29
User entered 'None (1)'	System	16 Aug 2020 16:02:29

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:16', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '13387b13-3c5c-4e43-a515-15c155a6e632'	System	16 Aug 2020 16:02:29
User entered 'No (N)'	System	16 Aug 2020 16:02:29

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:22', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '13387b13-3c5c-4e43-a515-15c155a6e632'	System	16 Aug 2020 16:02:29
User entered 'No (N)'	System	16 Aug 2020 16:02:29

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:24', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '13387b13-3c5c-4e43-a515-15c155a6e632'	System	16 Aug 2020 16:02:29
User entered 'None (1)'	System	16 Aug 2020 16:02:29

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:26', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '13387b13-3c5c-4e43-a515-15c155a6e632'	System	16 Aug 2020 16:02:29
User entered '16 Aug 2020 12:02'	System	16 Aug 2020 16:02:29

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 5'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:36', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2f8d705a-30ee-4a64-989b-cb88a59b0b84'	System	18 Aug 2020 16:08:30
User entered 'None (1)'	System	18 Aug 2020 16:08:30

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:38', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2f8d705a-30ee-4a64-989b-cb88a59b0b84'	System	18 Aug 2020 16:08:30
User entered 'No (N)'	System	18 Aug 2020 16:08:30

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:40', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2f8d705a-30ee-4a64-989b-cb88a59b0b84'	System	18 Aug 2020 16:08:30
User entered 'No (N)'	System	18 Aug 2020 16:08:30

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:43', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2f8d705a-30ee-4a64-989b-cb88a59b0b84'	System	18 Aug 2020 16:08:30
User entered 'None (1)'	System	18 Aug 2020 16:08:30

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:45', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2f8d705a-30ee-4a64-989b-cb88a59b0b84'	System	18 Aug 2020 16:08:30
User entered '17 Aug 2020 12:25'	System	18 Aug 2020 16:08:30

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 6'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:58

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:08:48', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '072b858f-f1bc-49f2-ab31-79da769851f5'	System	18 Aug 2020 16:09:01
User entered 'None (1)'	System	18 Aug 2020 16:09:01

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:08:51', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '072b858f-f1bc-49f2-ab31-79da769851f5'	System	18 Aug 2020 16:09:01
User entered 'No (N)'	System	18 Aug 2020 16:09:01

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:08:54', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '072b858f-f1bc-49f2-ab31-79da769851f5'	System	18 Aug 2020 16:09:01
User entered 'No (N)'	System	18 Aug 2020 16:09:01

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:08:57', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '072b858f-f1bc-49f2-ab31-79da769851f5'	System	18 Aug 2020 16:09:01
User entered 'None (1)'	System	18 Aug 2020 16:09:01

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:08:59', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '072b858f-f1bc-49f2-ab31-79da769851f5'	System	18 Aug 2020 16:09:01
User entered '18 Aug 2020 12:08'	System	18 Aug 2020 16:09:01

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 7'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:08', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3379b287-5175-40a5-8218-24bcf81a000b'	System	19 Aug 2020 16:03:20
User entered 'None (1)'	System	19 Aug 2020 16:03:20

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:11', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3379b287-5175-40a5-8218-24bcf81a000b'	System	19 Aug 2020 16:03:20
User entered 'No (N)'	System	19 Aug 2020 16:03:20

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:13', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3379b287-5175-40a5-8218-24bcf81a000b'	System	19 Aug 2020 16:03:20
User entered 'No (N)'	System	19 Aug 2020 16:03:20

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:15', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3379b287-5175-40a5-8218-24bcf81a000b'	System	19 Aug 2020 16:03:20
User entered 'None (1)'	System	19 Aug 2020 16:03:20

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:18', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3379b287-5175-40a5-8218-24bcf81a000b'	System	19 Aug 2020 16:03:20
User entered '19 Aug 2020 12:03'	System	19 Aug 2020 16:03:20

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:17:56', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd935fe0d-ef69-4937-a573-372bff4e0196'	System	13 Aug 2020 16:18:24
User entered 'None (0)'	System	13 Aug 2020 16:18:24

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:18:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd935fe0d-ef69-4937-a573-372bff4e0196'	System	13 Aug 2020 16:18:24
User entered 'None (0)'	System	13 Aug 2020 16:18:24

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:18:04', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd935fe0d-ef69-4937-a573-372bff4e0196'	System	13 Aug 2020 16:18:24
User entered 'None (0)'	System	13 Aug 2020 16:18:24

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:18:07', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd935fe0d-ef69-4937-a573-372bff4e0196'	System	13 Aug 2020 16:18:24
User entered 'None (0)'	System	13 Aug 2020 16:18:24

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:18:09', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd935fe0d-ef69-4937-a573-372bff4e0196'	System	13 Aug 2020 16:18:24
User entered 'None (0)'	System	13 Aug 2020 16:18:24

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:18:12', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd935fe0d-ef69-4937-a573-372bff4e0196'	System	13 Aug 2020 16:18:24
User entered 'None (0)'	System	13 Aug 2020 16:18:24

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:18:17', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd935fe0d-ef69-4937-a573-372bff4e0196'	System	13 Aug 2020 16:18:24
User entered 'No (N)'	System	13 Aug 2020 16:18:24

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:18:22', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd935fe0d-ef69-4937-a573-372bff4e0196'	System	13 Aug 2020 16:18:24
User entered '13 Aug 2020 12:18'	System	13 Aug 2020 16:18:24

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:48'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 14:18'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:52', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'b84d1c01-7135-4a94-99df-5082615ff8c8'	System	13 Aug 2020 19:15:17
User entered 'None (0)'	System	13 Aug 2020 19:15:17

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:54', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'b84d1c01-7135-4a94-99df-5082615ff8c8'	System	13 Aug 2020 19:15:17
User entered 'None (0)'	System	13 Aug 2020 19:15:17

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:57', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'b84d1c01-7135-4a94-99df-5082615ff8c8'	System	13 Aug 2020 19:15:17
User entered 'None (0)'	System	13 Aug 2020 19:15:17

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:15:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'b84d1c01-7135-4a94-99df-5082615ff8c8'	System	13 Aug 2020 19:15:17
User entered 'None (0)'	System	13 Aug 2020 19:15:17

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:15:03', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'b84d1c01-7135-4a94-99df-5082615ff8c8'	System	13 Aug 2020 19:15:17
User entered 'None (0)'	System	13 Aug 2020 19:15:17

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:15:06', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'b84d1c01-7135-4a94-99df-5082615ff8c8'	System	13 Aug 2020 19:15:17
User entered 'None (0)'	System	13 Aug 2020 19:15:17

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:15:12', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'b84d1c01-7135-4a94-99df-5082615ff8c8'	System	13 Aug 2020 19:15:17
User entered 'No (N)'	System	13 Aug 2020 19:15:17

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:15:15', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'b84d1c01-7135-4a94-99df-5082615ff8c8'	System	13 Aug 2020 19:15:17
User entered '13 Aug 2020 15:15'	System	13 Aug 2020 19:15:17

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 15:13'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 2'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:01:09', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '29c0ea73-5a9d-4b44-a803-eb4d8e8823d9'	System	14 Aug 2020 16:01:40
User entered 'None (0)'	System	14 Aug 2020 16:01:40

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:01:12', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '29c0ea73-5a9d-4b44-a803-eb4d8e8823d9'	System	14 Aug 2020 16:01:40
User entered 'None (0)'	System	14 Aug 2020 16:01:40

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:01:14', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '29c0ea73-5a9d-4b44-a803-eb4d8e8823d9'	System	14 Aug 2020 16:01:40
User entered 'None (0)'	System	14 Aug 2020 16:01:40

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:01:17', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '29c0ea73-5a9d-4b44-a803-eb4d8e8823d9'	System	14 Aug 2020 16:01:40
User entered 'None (0)'	System	14 Aug 2020 16:01:40

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:01:19', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '29c0ea73-5a9d-4b44-a803-eb4d8e8823d9'	System	14 Aug 2020 16:01:40
User entered 'None (0)'	System	14 Aug 2020 16:01:40

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:01:21', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '29c0ea73-5a9d-4b44-a803-eb4d8e8823d9'	System	14 Aug 2020 16:01:40
User entered 'None (0)'	System	14 Aug 2020 16:01:40

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:01:24', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '29c0ea73-5a9d-4b44-a803-eb4d8e8823d9'	System	14 Aug 2020 16:01:40
User entered 'No (N)'	System	14 Aug 2020 16:01:40

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:01:28', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '29c0ea73-5a9d-4b44-a803-eb4d8e8823d9'	System	14 Aug 2020 16:01:40
User entered '14 Aug 2020 12:01'	System	14 Aug 2020 16:01:40

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 3'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:13', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a87db230-b229-4c14-a0e2-2945aeef9ae0'	System	15 Aug 2020 16:01:34
User entered 'None (0)'	System	15 Aug 2020 16:01:34

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:15', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a87db230-b229-4c14-a0e2-2945aeef9ae0'	System	15 Aug 2020 16:01:34
User entered 'None (0)'	System	15 Aug 2020 16:01:34

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:18', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a87db230-b229-4c14-a0e2-2945aeef9ae0'	System	15 Aug 2020 16:01:34
User entered 'None (0)'	System	15 Aug 2020 16:01:34

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:20', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a87db230-b229-4c14-a0e2-2945aeef9ae0'	System	15 Aug 2020 16:01:34
User entered 'None (0)'	System	15 Aug 2020 16:01:34

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:22', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a87db230-b229-4c14-a0e2-2945aeef9ae0'	System	15 Aug 2020 16:01:34
User entered 'None (0)'	System	15 Aug 2020 16:01:34

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:24', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a87db230-b229-4c14-a0e2-2945aeef9ae0'	System	15 Aug 2020 16:01:34
User entered 'None (0)'	System	15 Aug 2020 16:01:34

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:27', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a87db230-b229-4c14-a0e2-2945aeef9ae0'	System	15 Aug 2020 16:01:34
User entered 'No (N)'	System	15 Aug 2020 16:01:34

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:30', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a87db230-b229-4c14-a0e2-2945aeef9ae0'	System	15 Aug 2020 16:01:34
User entered '15 Aug 2020 12:01'	System	15 Aug 2020 16:01:34

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 4'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:34', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '40faa101-9516-4b13-b680-732b3106dc25'	System	16 Aug 2020 16:02:55
User entered 'None (0)'	System	16 Aug 2020 16:02:55

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:37', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '40faa101-9516-4b13-b680-732b3106dc25'	System	16 Aug 2020 16:02:55
User entered 'None (0)'	System	16 Aug 2020 16:02:55

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:39', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '40faa101-9516-4b13-b680-732b3106dc25'	System	16 Aug 2020 16:02:55
User entered 'None (0)'	System	16 Aug 2020 16:02:55

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:41', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '40faa101-9516-4b13-b680-732b3106dc25'	System	16 Aug 2020 16:02:55
User entered 'None (0)'	System	16 Aug 2020 16:02:55

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:43', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '40faa101-9516-4b13-b680-732b3106dc25'	System	16 Aug 2020 16:02:55
User entered 'None (0)'	System	16 Aug 2020 16:02:55

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:45', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '40faa101-9516-4b13-b680-732b3106dc25'	System	16 Aug 2020 16:02:55
User entered 'None (0)'	System	16 Aug 2020 16:02:55

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:48', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '40faa101-9516-4b13-b680-732b3106dc25'	System	16 Aug 2020 16:02:55
User entered 'No (N)'	System	16 Aug 2020 16:02:55

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:52', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '40faa101-9516-4b13-b680-732b3106dc25'	System	16 Aug 2020 16:02:55
User entered '16 Aug 2020 12:02'	System	16 Aug 2020 16:02:55

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 5'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:49', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0d069e12-44cd-4212-9164-406b3dddfcd2'	System	18 Aug 2020 16:08:31
User entered 'None (0)'	System	18 Aug 2020 16:08:31

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:51', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0d069e12-44cd-4212-9164-406b3dddfcd2'	System	18 Aug 2020 16:08:31
User entered 'None (0)'	System	18 Aug 2020 16:08:31

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:55', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0d069e12-44cd-4212-9164-406b3dddfcd2'	System	18 Aug 2020 16:08:31
User entered 'None (0)'	System	18 Aug 2020 16:08:31

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:57', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0d069e12-44cd-4212-9164-406b3dddfcd2'	System	18 Aug 2020 16:08:31
User entered 'None (0)'	System	18 Aug 2020 16:08:31

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:59', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0d069e12-44cd-4212-9164-406b3dddfcd2'	System	18 Aug 2020 16:08:31
User entered 'None (0)'	System	18 Aug 2020 16:08:31

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:26:01', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0d069e12-44cd-4212-9164-406b3dddfcd2'	System	18 Aug 2020 16:08:31
User entered 'None (0)'	System	18 Aug 2020 16:08:31

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:26:05', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0d069e12-44cd-4212-9164-406b3dddfcd2'	System	18 Aug 2020 16:08:31
User entered 'No (N)'	System	18 Aug 2020 16:08:31

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:26:10', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0d069e12-44cd-4212-9164-406b3dddfcd2'	System	18 Aug 2020 16:08:31
User entered '17 Aug 2020 12:26'	System	18 Aug 2020 16:08:31

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 6'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:09:06', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '6e46eb69-0088-42e2-9968-e152554a3249'	System	18 Aug 2020 16:09:29
User entered 'None (0)'	System	18 Aug 2020 16:09:29

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:09:09', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '6e46eb69-0088-42e2-9968-e152554a3249'	System	18 Aug 2020 16:09:29
User entered 'None (0)'	System	18 Aug 2020 16:09:29

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:09:11', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '6e46eb69-0088-42e2-9968-e152554a3249'	System	18 Aug 2020 16:09:29
User entered 'None (0)'	System	18 Aug 2020 16:09:29

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:09:14', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '6e46eb69-0088-42e2-9968-e152554a3249'	System	18 Aug 2020 16:09:29
User entered 'None (0)'	System	18 Aug 2020 16:09:29

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:09:17', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '6e46eb69-0088-42e2-9968-e152554a3249'	System	18 Aug 2020 16:09:29
User entered 'None (0)'	System	18 Aug 2020 16:09:29

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:09:19', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '6e46eb69-0088-42e2-9968-e152554a3249'	System	18 Aug 2020 16:09:29
User entered 'None (0)'	System	18 Aug 2020 16:09:29

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:09:22', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '6e46eb69-0088-42e2-9968-e152554a3249'	System	18 Aug 2020 16:09:29
User entered 'No (N)'	System	18 Aug 2020 16:09:29

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:09:24', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '6e46eb69-0088-42e2-9968-e152554a3249'	System	18 Aug 2020 16:09:29
User entered '18 Aug 2020 12:09'	System	18 Aug 2020 16:09:29

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 7'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:22', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c1a592a1-30ed-4172-9fc1-c113bf07a388'	System	19 Aug 2020 16:03:42
User entered 'None (0)'	System	19 Aug 2020 16:03:42

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:23', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c1a592a1-30ed-4172-9fc1-c113bf07a388'	System	19 Aug 2020 16:03:42
User entered 'None (0)'	System	19 Aug 2020 16:03:42

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:25', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c1a592a1-30ed-4172-9fc1-c113bf07a388'	System	19 Aug 2020 16:03:42
User entered 'None (0)'	System	19 Aug 2020 16:03:42

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:26', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c1a592a1-30ed-4172-9fc1-c113bf07a388'	System	19 Aug 2020 16:03:42
User entered 'None (0)'	System	19 Aug 2020 16:03:42

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:28', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c1a592a1-30ed-4172-9fc1-c113bf07a388'	System	19 Aug 2020 16:03:42
User entered 'None (0)'	System	19 Aug 2020 16:03:42

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:29', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c1a592a1-30ed-4172-9fc1-c113bf07a388'	System	19 Aug 2020 16:03:42
User entered 'None (0)'	System	19 Aug 2020 16:03:42

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:35', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c1a592a1-30ed-4172-9fc1-c113bf07a388'	System	19 Aug 2020 16:03:42
User entered 'No (N)'	System	19 Aug 2020 16:03:42

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:37', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c1a592a1-30ed-4172-9fc1-c113bf07a388'	System	19 Aug 2020 16:03:42
User entered '19 Aug 2020 12:03'	System	19 Aug 2020 16:03:42

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:02:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	21 Aug 2020 18:24:18

US3372110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Alexandra Arango (b) (4) (b) (4)	21 Aug 2020 18:24:18

US3372110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[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 18:24:18

US3372110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	21 Aug 2020 18:24:18

US3372110

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

[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 18:24:27

US3372110

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:24:27

US3372110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Peter Jacob (b) (4)	23 Sep 2020 19:51:53
User entered 'No (N)'	Peter Jacob (b) (4)	23 Sep 2020 19:47:57

US3372110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '28 Aug 2020' reason for change: Data Entry Error	Peter Jacob (b) (4)	23 Sep 2020 19:51:53
User entered empty.	Peter Jacob (b) (4)	23 Sep 2020 19:47:57

US3372110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Peter Jacob (b) (4)	23 Sep 2020 19:51:53
reason for change: Data Entry Error	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Sep 2020 19:47:57
	(b) (4)	

US3372110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:47:57

US3372110

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

[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 20:04:05

US3372110

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 20:04:05

US3372110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	03 Sep 2020 20:04:25

US3372110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '3 Sep 2020'	Alexandra Arango (b) (4) (b) (4)	03 Sep 2020 20:04:25

US3372110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[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 20:04:25

US3372110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	03 Sep 2020 20:04:25

US3372110

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

[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 20:04:28

US3372110

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 20:04:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 13:48:38

US3372110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 13:48:38

US3372110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Sep 2020 13:48:38

US3372110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	15 Sep 2020 13:48:38

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '09:16'	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '15 Sep 2020 09:16'	System	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '84'	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '17'	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '123'	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '88'	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:02:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:02:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:48

US3372110

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:48

US3372110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 13:49:15

US3372110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

[If No, reason not given](#)

Audit	User	Time (GMT)
User closed query 'Please complete applicable forms associated with confirmed COVID-19 diagnosis. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 20:29:28
Query 'Please complete applicable forms associated with confirmed COVID-19 diagnosis. Thank you.' answered with 'patient is asymptomatic ' (Site from DM).	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 15:21:54
User opened query 'Please complete applicable forms associated with confirmed COVID-19 diagnosis. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 15:41:55
User entered 'Confirmed COVID-19 (COVID)'	(b) (4), (b) (6)	15 Sep 2020 13:49:15

US3372110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

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)	15 Sep 2020 13:49:15

US3372110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 13:49:15

US3372110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 13:49:15

US3372110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 13:49:15

US3372110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 13:49:15

US3372110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 13:49:15

US3372110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 13:49:15

US3372110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 13:49:15

US3372110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:10:49

US3372110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:10:49

US3372110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '10:04' reason for change: Data Entry Error	Peter Jacob (b) (4)	02 Oct 2020 19:10:52
User entered '10:02'	Peter Jacob (b) (4)	02 Oct 2020 19:10:49

US3372110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '15 Sep 2020 10:04'	System	02 Oct 2020 19:10:52
User entered '15 Sep 2020 10:02'	System	02 Oct 2020 19:10:49

US3372110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:02:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:11:04

US3372110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:02:58

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:11:04

US3372110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:02:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:11:04

US3372110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:02:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:02'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:11:04

US3372110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '15 Sep 2020 10:02'	System	02 Oct 2020 19:11:04

US3372110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:02:58

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:11:04

US3372110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:02:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:11:04

US3372110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:02:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:11:04

US3372110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:11:04

US3372110

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

[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 19:22:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 19:22:28

US3372110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:47:27

US3372110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:47:27

US3372110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:47:27

US3372110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:47:27

US3372110

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:47:34

US3372110

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 19:47:34

US3372110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:37

US3372110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:37

US3372110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:37

US3372110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:37

US3372110

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Acosta (b) (4) (b) (4)	08 Oct 2020 14:52:51

US3372110

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 14:52:51

US3372110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:42

US3372110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:42

US3372110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:42

US3372110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:02:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:42

US3372110

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Acosta (b) (4) (b) (4)	08 Oct 2020 14:52:58

US3372110

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 14:52:58

US3372110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Acosta (b) (4) (b) (4)	08 Oct 2020 14:53:10

US3372110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '08 Oct 2020' reason for change: Data Entry Error	Peter Jacob (b) (4)	15 Oct 2020 21:08:51
User entered '8 Oct 2020'	Elena Acosta (b) (4)	08 Oct 2020 14:53:10

US3372110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

[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)	08 Oct 2020 14:53:10

US3372110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:02:58

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	08 Oct 2020 14:53:10

US3372110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:55

US3372110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:55

US3372110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:55

US3372110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 21:08:55

US3372110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:55

US3372110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:55

US3372110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:55

US3372110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

Pulse (xxx)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:55

US3372110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 21:08:55

US3372110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:55

US3372110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 21:08:55

US3372110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:55

US3372110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 21:08:55

US3372110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:55

US3372110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:02:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 21:08:55

US3372110

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:09:04

US3372110

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:02:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:09:04

US3372110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:09:15

US3372110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Oct 2020'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:09:15

US3372110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:06'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:09:15

US3372110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:06'	System	15 Oct 2020 21:09:15

US3372110

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:09:19

US3372110

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:02:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 21:09:19

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 64'	System	13 Aug 2020 15:32:14

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-15T12:01:05', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '51cdaf9f-8df1-4be1-a33c-f1721e3fee28'	System	15 Oct 2020 16:01:59
User entered 'No (N)'	System	15 Oct 2020 16:01:59

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-15T12:01:11', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '51cdaf9f-8df1-4be1-a33c-f1721e3fee28'	System	15 Oct 2020 16:01:59
User entered 'No (N)'	System	15 Oct 2020 16:01:59

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-15T12:01:18', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '51cdaf9f-8df1-4be1-a33c-f1721e3fee28' User entered '15 Oct 2020 12:01:18'	System	15 Oct 2020 16:01:59
	System	15 Oct 2020 16:01:59

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 15:32:14

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 71'	System	13 Aug 2020 15:32:14

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-20T05:33:05', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd60b6158-3876-4ef4-9c02-0c855dae74a0'	System	20 Oct 2020 09:33:26
User entered 'No (N)'	System	20 Oct 2020 09:33:26

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-20T05:33:13', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd60b6158-3876-4ef4-9c02-0c855dae74a0'	System	20 Oct 2020 09:33:26
User entered 'No (N)'	System	20 Oct 2020 09:33:26

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-20T05:33:20', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd60b6158-3876-4ef4-9c02-0c855dae74a0' User entered '20 Oct 2020 05:33:20'	System	20 Oct 2020 09:33:26
	System	20 Oct 2020 09:33:26

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 15:32:14

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 78'	System	13 Aug 2020 15:32:14

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-29T12:00:44', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '44681d75-9fdd-4247-8896-ff3c78cf40c0'	System	29 Oct 2020 16:02:12
User entered 'No (N)'	System	29 Oct 2020 16:02:12

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-29T12:00:50', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '44681d75-9fdd-4247-8896-ff3c78cf40c0'	System	29 Oct 2020 16:02:12
User entered 'Yes (Y)'	System	29 Oct 2020 16:02:12

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-29T12:01:05', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '44681d75-9fdd-4247-8896-ff3c78cf40c0'	System	29 Oct 2020 16:02:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Oct 2020 16:02:12

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-29T12:01:15', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '44681d75-9fdd-4247-8896-ff3c78cf40c0'	System	29 Oct 2020 16:02:12
User entered '29 Oct 2020 12:01:15'	System	29 Oct 2020 16:02:12

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 15:32:14

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 92'	System	13 Aug 2020 15:32:14

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-10T00:01:46', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '353448ef-4fb2-4308-bc81-6ed248a06bb4'	System	10 Nov 2020 05:02:46
User entered 'No (N)'	System	10 Nov 2020 05:02:46

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-10T00:01:57', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '353448ef-4fb2-4308-bc81-6ed248a06bb4'	System	10 Nov 2020 05:02:46
User entered 'Yes (Y)'	System	10 Nov 2020 05:02:46

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-10T00:02:28', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '353448ef-4fb2-4308-bc81-6ed248a06bb4'	System	10 Nov 2020 05:02:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Nov 2020 05:02:46

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-10T00:02:35', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '353448ef-4fb2-4308-bc81-6ed248a06bb4' User entered '10 Nov 2020 00:02:35'	System	10 Nov 2020 05:02:46
	System	10 Nov 2020 05:02:46

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 15:32:14

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 99'	System	13 Aug 2020 15:32:14

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-17T03:25:58', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0ab64f89-8489-43ee-aac3-0160013b51da'	System	17 Nov 2020 08:26:19
User entered 'No (N)'	System	17 Nov 2020 08:26:19

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-17T03:26:07', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0ab64f89-8489-43ee-aac3-0160013b51da'	System	17 Nov 2020 08:26:19
User entered 'No (N)'	System	17 Nov 2020 08:26:19

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-17T03:26:15', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0ab64f89-8489-43ee-aac3-0160013b51da' User entered '17 Nov 2020 03:26:15'	System	17 Nov 2020 08:26:19
	System	17 Nov 2020 08:26:19

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 15:32:14

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '10 Oct 2020 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '14 Oct 2020 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '17 Oct 2020 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '21 Oct 2020 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '24 Oct 2020 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '28 Oct 2020 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '31 Oct 2020 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '04 Nov 2020 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '07 Nov 2020 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '11 Nov 2020 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '14 Nov 2020 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '18 Nov 2020 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-24T02:29:28', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '09eabffa-50b3-4f74-9f1b-f5f84c737ac1'	System	24 Nov 2020 07:29:42
User entered 'No (N)'	System	24 Nov 2020 07:29:42

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-24T02:29:32', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '09eabffa-50b3-4f74-9f1b-f5f84c737ac1'	System	24 Nov 2020 07:29:42
User entered 'No (N)'	System	24 Nov 2020 07:29:42

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-24T02:29:37', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '09eabffa-50b3-4f74-9f1b-f5f84c737ac1' User entered '24 Nov 2020 02:29:37'	System	24 Nov 2020 07:29:42

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 05:45:04

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:02:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:02:58

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	13 Nov 2020 20:17:49

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Acute sinusitis, LLT: Acute sinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 20:21:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 20:21:52
Data point term sent to Coder	System	13 Nov 2020 20:21:33
User entered 'Acute Sinusitis'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[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 19:54:02
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 17:44:16
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Torres (b) (4)	18 Nov 2020 17:44:06
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 06:23:12
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[None](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:02:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 20:24:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 20:24:50
Data point term sent to Coder	System	13 Nov 2020 20:23:39
User entered 'Sinus Infection'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 19:54:10
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' answered with 'AE is not related to study procedure.' (Site from DM).	Jennifer Torres (b) (4)	18 Nov 2020 17:45:02
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Torres (b) (4)	18 Nov 2020 17:44:56
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:08:38
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[None](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:02:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 20:23:24

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:14
User entered 'USA-US056-2020-mRNA-1273-P301000007'	System	16 Nov 2020 21:53:09
User entered 'New'	(b) (4), (b) (6)	16 Nov 2020 21:53:09

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 20:26:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 20:26:35
Data point term sent to Coder	System	13 Nov 2020 20:25:50
User entered 'Covid 19'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[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 19:54:19
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 17:45:26
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Torres (b) (4)	18 Nov 2020 17:45:21
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 06:10:26
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Mary Sergalis (b) (4) [REDACTED] [REDACTED]	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[None](#)

Audit	User	Time (GMT)
User entered '1'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 20:25:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 20:25:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	13 Nov 2020 20:25:21
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 20:25:13
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'no treatment was required since subject was asymptomatic' (Site from Safety).	Peter Jacob (b) (4)	24 Nov 2020 22:52:01
Query 'PV Query: Please complete the COVID-19 Assessments tab, including results of COVID-19 diagnostic test, symptoms log, and severity assessment.' answered with 'subject was asymptomatic and did not require any illness visits' (Site from Safety).	Peter Jacob (b) (4)	24 Nov 2020 22:51:27
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:12:26
User opened query 'PV Query: Please complete the COVID-19 Assessments tab, including results of COVID-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:12:10
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:02:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 20:25:13

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:02:58

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:11:38

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:16:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:16:54
Data point term sent to Coder	System	02 Oct 2020 19:15:57
User entered 'losartan'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:02:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:23:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:23:43
Data point term sent to Coder	System	02 Oct 2020 19:23:10
User entered 'rosuvastatin'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypercholesterolemia'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '24 Jul 2020'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:02:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 04:27:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 04:27:48
Data point term sent to Coder	System	02 Oct 2020 19:24:11
User entered 'testosterone injections'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

[Indication](#)

Audit	User	Time (GMT)
User entered 'low testosterone'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 100 mg, 200 mg, etc) instead of amount in mL, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 05:06:05
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 100 mg, 200 mg, etc) instead of amount in mL, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'DOSE UNIT IS CORRECT AS RECORDED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:46:06
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 100 mg, 200 mg, etc) instead of amount in mL, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:19:32
User entered 'mL (mL)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

[Frequency](#)

Audit	User	Time (GMT)
User entered 'every week (QS)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:02:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 19:27:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 19:27:51
Data point term sent to Coder	System	02 Oct 2020 19:26:13
User entered 'singulair'	Peter Jacob (b) (4)	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

[Indication](#)

Audit	User	Time (GMT)
User entered 'chronic sinusitis'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:02:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 19:29:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 19:29:47
Data point term sent to Coder	System	02 Oct 2020 19:29:23
User entered 'azithromycin'	Peter Jacob (b) (4)	02 Oct 2020 19:28:25
	(b) (4)	

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Requery: Response noted, however no AE has been recorded in AE form for this indication. Please review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 05:08:19
Query 'Per CDM: Requery: Response noted, however no AE has been recorded in AE form for this indication. Please review and update accordingly. Thank you.' answered with 'Updated' (Site from DM).	Mary Sergalis (b) (4)	13 Nov 2020 20:26:05
User opened query 'Per CDM: Requery: Response noted, however no AE has been recorded in AE form for this indication. Please review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 08:17:15
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 08:15:22
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'SINUS INFECTION IS RECOGNIZED AS AN SOLICITED EVENT AS RECORDED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:47:04
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:20:22
User entered 'sinus infection'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '250'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '04 Sep 2020'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Requery: Response noted, however as per protocol the indication is not a solicited event. Please consider to update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:49:53
Query 'Per CDM: Requery: Response noted, however as per protocol the indication is not a solicited event. Please consider to update accordingly. Thank you.' answered with 'Updated' (Site from DM).	Mary Sergalis (b) (4)	13 Nov 2020 20:26:25
User entered 'No (N)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	13 Nov 2020 20:26:17
User opened query 'Per CDM: Requery: Response noted, however as per protocol the indication is not a solicited event. Please consider to update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 08:45:04
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 08:42:36
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'SINUS INFECTION IS RECOGNIZED AS AN SOLICITED EVENT. SUBJECT DID SEEK MEDICAL TREATMENT AS RECORDED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:50:51
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:20:30
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:02:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 05:26:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 05:26:43
Data point term sent to Coder	System	02 Oct 2020 19:30:25
User entered 'methylprednisolone'	Peter Jacob (b) (4)	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 16:56:41
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'ACUTE SINUSITIS IS RECOGNIZED AS AN SOLICITED EVENT AS RECORDED ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:53:05
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:20:59
User entered 'acute sinusitis'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '4'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

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

Audit	User	Time (GMT)
User entered '04 Sep 2020'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 16:56:50
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'ACUTE SINUSITIS IS RECOGNIZED AS AN SOLICITED EVENT. SUBJECT DID SEEK MEDICAL TREATMENT AS WELL AS RECORDED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:54:59
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:21:05
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:02:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:02:58

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:11:16

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'USA-US056-2020-MRNA-1273-P301000007'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'Mira'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'Baron'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered '2277 Palm beach Lakes Blvd'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'West Palm Beach'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered '33409'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	16 Nov 2020 21:53:28

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 21:53:28

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'USA-US056-2020-MRNA-1273-P301000007'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'Mira'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'Baron'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered '2277 Palm beach Lakes Blvd'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'West Palm Beach'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered '33409'	System	16 Nov 2020 21:53:09

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	16 Nov 2020 21:53:28

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:02:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 21:53:28

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:02:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '16/Nov/2020 21:53'	System	16 Nov 2020 21:53:28

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:02:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 21:53:28