

US3732110 (Prod: eStudySite - La Mesa - PPDS)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:12:49

All time stamps listed in this document are displayed in GMT

US3732110

Form: Participant Creation

Generated On: 26 Nov 2020 11:12:49

[Participant ID](#)

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

US3732110

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

Date of Birth (MMM yyyy)	(b) (6) 1939
Age	81
Age Units	YEARS
Age (Derived)	81
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

Date of Informed Consent (<i>dd MMM yyyy</i>)	20 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:12:49

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:12:49

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

Condition	SOTALOL DRUG ALLERGY
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

Condition	VICODIN DRUG ALLERGY
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:49

Condition	LISINOPRIL DRUG ALLERGY
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:49

Condition	NAPROXEN DRUG ALLERGY
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:49

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:49

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:12:49

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 1958
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 1958
Start Year (derived)	1958
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:12:49

Condition	ACTINIC KERATOSIS - SCALP
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:12:49

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:12:49

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:12:49

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:12:49

Condition	BENIGN PROSTATIC HYPERTROPHY
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:12:49

Condition	AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:12:49

Condition	GOUT RIGHT BIG TOE
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:05 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 12:05
Height (<i>xxx.x</i>)	183.0 cm
Weight (<i>xxx.x</i>)	96.7 kg
BMI (<i>xxx.x</i>)	28.87515 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)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

> 65 YEARS OLD, CAN'T
SHELTER IN PLACE LIVES IN
HIGH DENSITY HOUSING

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 187186

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☐
 >=65 years ☒

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☒ No ☐

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:49

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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)	20 AUG 2020
Time of assessment (00:00-23:59)	12:05 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 12:05
Temperature (xxx.x)	98.5 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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)	20 AUG 2020
Time of assessment (00:00-23:59)	13:29 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 13:29
Temperature (xxx.x)	97.5 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

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.

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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) 20 AUG 2020

What was the treatment time? (00:00-23:59) 12:59 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 12:59

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

20 AUG 2020

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

12:32 (24 HR)

Collection date and time (derived)

20 AUG 2020 12:32

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:12:49

Collection date (<i>dd MMM yyyy</i>)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:49	20 AUG 2020 12:49
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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

97.5 °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

20 AUG 2020 13:32

PC Open Date & Time

20 AUG 2020 13:19

PC Close Date & Time

20 AUG 2020 15:49

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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 95.1 °F

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

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

PC Time Stamp	21 AUG 2020 08:11
PC Open Date & Time	20 AUG 2020 16:44
PC Close Date & Time	21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 09:44

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 08:33

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

25 AUG 2020 20:51

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 11:01

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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

20 AUG 2020 13:34

PC Open Date & Time

20 AUG 2020 13:19

PC Close Date & Time

20 AUG 2020 15:49

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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

21 AUG 2020 08:14

PC Open Date & Time

20 AUG 2020 16:44

PC Close Date & Time

21 AUG 2020 11:59

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

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

22 AUG 2020 09:44

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

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

23 AUG 2020 08:34

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

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

25 AUG 2020 20:51

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

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

27 AUG 2020 11:01

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 13:35
PC Open Date & Time	20 AUG 2020 13:19
PC Close Date & Time	20 AUG 2020 15:49

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 08:14
PC Open Date & Time	20 AUG 2020 16:44
PC Close Date & Time	21 AUG 2020 11:59

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

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 ☒

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

Yes ☐	
PC Time stamp	22 AUG 2020 09:45
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

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 ☒

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

Yes ☐	
PC Time stamp	23 AUG 2020 08:34
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

		Yes ☐
PC Time stamp		
PC Open Date & Time		23 AUG 2020 12:00
PC Close Date & Time		24 AUG 2020 11:59

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

		Yes ☐
PC Time stamp		
PC Open Date & Time		24 AUG 2020 12:00
PC Close Date & Time		25 AUG 2020 11:59

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

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 ☒

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

Yes ☐	
PC Time stamp	25 AUG 2020 20:52
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

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 ☒

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

Yes ☐	
PC Time stamp	27 AUG 2020 11:02
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3732110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732110

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732110

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732110

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 10:25
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	95 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	55 mmHg
Diastolic Blood Pressure units	MMHG

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	11:33 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 11:33
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3732110

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3732110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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)	17 SEP 2020
What was the treatment time? (00:00-23:59)	11:03 (24 HR)
Treatment Date and Time (derived)	17 SEP 2020 11:03
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

US3732110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	17 SEP 2020
Collection time (<i>00:00-23:59</i>)	10:38 (24 HR)
Collection date and time (derived)	17 SEP 2020 10:38

US3732110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:12:49

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:30	17 SEP 2020 10:30
Nasopharyngeal Swab 2	No		

US3732110

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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

17 SEP 2020 11:43

PC Open Date & Time

17 SEP 2020 11:23

PC Close Date & Time

17 SEP 2020 13:53

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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 95.5 °F

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

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

PC Time Stamp	18 SEP 2020 10:10
PC Open Date & Time	17 SEP 2020 14:48
PC Close Date & Time	18 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 10:22

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

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

19 SEP 2020 20:08

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 21:56

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

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

96.0 °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

21 SEP 2020 13:11

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 21:04

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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

17 SEP 2020 11:44

PC Open Date & Time

17 SEP 2020 11:23

PC Close Date & Time

17 SEP 2020 13:53

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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

18 SEP 2020 10:11

PC Open Date & Time

17 SEP 2020 14:48

PC Close Date & Time

18 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

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

19 SEP 2020 10:23

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 20:09

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

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

20 SEP 2020 21:57

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

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

21 SEP 2020 13:11

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

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

22 SEP 2020 21:04

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 11:44
PC Open Date & Time	17 SEP 2020 11:23
PC Close Date & Time	17 SEP 2020 13:53

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 10:12
PC Open Date & Time	17 SEP 2020 14:48
PC Close Date & Time	18 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

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 ☒

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

Yes ☐	
PC Time stamp	19 SEP 2020 10:23
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

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 ☒

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

Yes ☐	
PC Time stamp	19 SEP 2020 20:09
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

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 ☒

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

Yes ☐	
PC Time stamp	20 SEP 2020 21:57
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

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 ☒

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

Yes ☐	
PC Time stamp	21 SEP 2020 13:12
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

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 ☒

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

Yes ☐	
PC Time stamp	22 SEP 2020 21:05
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

Yes ☐

PC Time stamp

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3732110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732110

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732110

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732110

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3732110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	16 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:45 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 11:45
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732110

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

US3732110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	16 OCT 2020
Collection time (<i>00:00-23:59</i>)	12:20 (24 HR)
Collection date and time (derived)	16 OCT 2020 12:20

US3732110

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	22 OCT 2020 12:02:18
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

29 OCT 2020 13:49:55

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 08:10:49

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

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27 JAN 2021 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

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30 JAN 2021 00:01

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03 FEB 2021 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

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17 FEB 2021 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 MAR 2021 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

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17 MAR 2021 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

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24 MAR 2021 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

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31 MAR 2021 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

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10 APR 2021 00:01

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14 APR 2021 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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21 APR 2021 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

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02 FEB 2022 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

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09 FEB 2022 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

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US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

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13 APR 2022 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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20 APR 2022 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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27 APR 2022 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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04 MAY 2022 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

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06 JUL 2022 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3732110

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

Was Contact Attempted?

Yes ☒

No ☐

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

12 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732110

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732110

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

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

US3732110

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3732110

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:12:49

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3732110

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:12:49

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

AEID	USA-US102-2020-MRNA-1273-P30 1000003
Adverse event	DISPLACED AUTOMATED IMPLANTABLE CARDIOVERTER DEFIBRILLATOR LEAD
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)	08 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	08 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	09 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	DURING DAY 57 SUBJECT REPORTED IMPLANTABLE DEVICE REPLACEMENT AND DURING THIS PROCEDURE IT WAS NOTED SUBJECT HAD A DISPLACED AICD LEAD WHICH RESULTED IN ONE OVERNIGHT STAY FOR OBSERVATION

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

AEID	
Adverse event	POST SURGICAL PAIN BILATERAL SHOULDERS RELATED TO DISPLACE AUTOMATED IMPLANTABLE CARDIOVERTER DEFIBRILLATOR LEAD PROCEDURE
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)	08 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	29 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	
v6.020 DTW (1102)	349 of 1858

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

	Yes ☐
	No ☐
	Unknown ☐
Number of Days in ICU	
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)	1
Admitted to ICU Derived (CSA Programming Field Only)	
v6.020 DTW (1102)	350 of 1858

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:12:49

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

Yes ☒

No ☐

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

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPOTHYROIDISM
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 ☐

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

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 2000
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 ☒

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

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

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

	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 1990
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	☒

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

Name of Medication	METROPOL SUCCINATE ER
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

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 1995
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 ☒

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

Name of Medication	ALPHA LIPOIC ACID
Prophylaxis	Yes ☒ No ☐
Indication	VITAMIN DEFICIENCY
Dose per administration	300
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 ☐

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

	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 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

Name of Medication	FLECAINIDE ACETATE (TAMBOCOR)
Prophylaxis	Yes ☐ No ☒
Indication	ARRHYTHMIA VENTRICULAR TACHYCARDIA
Dose per administration	100
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

Name of Medication	TAMULOSIN (FLOMAX)
Prophylaxis	Yes ☐ No ☒
Indication	BENIGN PROSTATIC HYPERPLASIA
Dose per administration	0.4
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

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

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

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

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

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 1980
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 ☒

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

Name of Medication	SIMVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERLIPIDEMIA
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

	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 1980
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	☒

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

Name of Medication	KEFLEX
Prophylaxis	Yes ☐ No ☒
Indication	PACEMAKER REPLACEMENT PROCEDURE
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 ☐

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	16 OCT 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ☒
Indication	PACEMAKER REPLACEMENT PROCEDURE
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

Name of Medication	COLCHICINE
Prophylaxis	Yes ☐ No ☒
Indication	GOUT RIGHT BIG TOE
Dose per administration	0.6
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 ☐

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3732110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:12:49

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3732110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:12:49

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
08 OCT 2020	PACEMAKER REPLACEMENT	Medical History	
08 OCT 2020	AUTOMATED IMPLANTABLE CARDIOVERTER DEFIBRILLATOR LEAD REPLACEMENT	Medical History	

US3732110

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:12:49

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

US3732110

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

SAEID	USA-US102-2020-MRNA-1273-P301000003
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:12:49

SAEID	USA-US102-2020-MRNA-1273-P301000003
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	19/OCT/2020 12:19
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

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:12:49

SAEID	USA-US102-2020-MRNA-1273-P301000003
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	10/NOV/2020 14:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:12:49

SAEID	USA-US102-2020-MRNA-1273-P301000003
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	
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.	False

Audit

US3732110 (Prod: eStudySite - La Mesa - PPDS)

US3732110

Form: Participant Creation

Generated On: 26 Nov 2020 11:12:49

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:25
User entered 'US3732110'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:19:36

US3732110

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:59:42
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:32:01

US3732110

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:59:42
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:19:37

US3732110

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:59:42
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:32:01

US3732110

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	21 Aug 2020 17:32:01

US3732110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered (b) (6) 1939'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:19:38

US3732110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered '81'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

US3732110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	21 Aug 2020 17:38:21

US3732110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '81'	System	20 Aug 2020 20:03:45

US3732110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

Sex

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered 'Male (M)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

US3732110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

US3732110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered '1'	Lauren Arnett (b) (4)	21 Aug 2020 17:38:21
	(b) (4)	

US3732110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 17:38:21
	(b) (4)	

US3732110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

US3732110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

US3732110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 17:38:21
	(b) (4)	

US3732110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

US3732110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

US3732110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 17:38:21
	(b) (4)	

US3732110

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

US3732110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:16:34
User entered '20 Aug 2020'	Lauren Arnett (b) (4)	20 Aug 2020 20:03:45
	(b) (4)	

US3732110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	20 Aug 2020 20:03:45

US3732110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '2020'	System	20 Aug 2020 20:03:45

US3732110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:16:34
User entered 'Amendment 2 (2)'	Lauren Arnett (b) (4)	20 Aug 2020 20:03:45
	(b) (4)	

US3732110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:16:34
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:03:45

US3732110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:16:34
User entered empty.	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:03:45

US3732110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:16:34
User entered empty.	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:03:45

US3732110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:16:34
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:03:45

US3732110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:16:34
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:19:37

US3732110

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:03:50

US3732110

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:16:41
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:03:50

US3732110

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:12:49

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:16:47
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:33:09

US3732110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 11:45:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 11:45:32
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
Data point term sent to Coder	System	20 Oct 2020 15:45:22
Coding entries removed.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:45:02
User entered 'sotalol drug allergy' reason for change: Data Entry Error	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:45:02
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 22:27:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 22:27:20
Data point term sent to Coder	System	21 Aug 2020 17:35:37
User entered 'allergy to sotalol'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:02

US3732110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 2000'	Lauren Arnett (b) (4)	21 Aug 2020 17:35:02
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:02

US3732110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:02

US3732110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:02

US3732110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:02

US3732110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	21 Aug 2020 17:35:02

US3732110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '2000'	System	21 Aug 2020 17:35:02

US3732110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 17:35:02

US3732110

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 17:35:02

US3732110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 15:47:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	20 Oct 2020 15:47:47
Data point term sent to Coder	System	20 Oct 2020 15:46:23
Coding entries removed.	Amara Yilmaz (b) (4)	20 Oct 2020 15:45:25
User entered 'vicodin drug allergy' reason for change: Data Entry Error	(b) (4)	20 Oct 2020 15:45:25
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\23.0.	Amara Yilmaz (b) (4)	20 Oct 2020 15:45:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	14 Oct 2020 19:21:34
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 19:21:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	17 Sep 2020 07:53:59
Data point term sent to Coder	System	17 Sep 2020 07:53:59
User entered 'allergy to hydrocodone-acetaminophen'	Lauren Arnett (b) (4)	16 Sep 2020 21:24:43
DataPoint activated with code reason code Data required.	(b) (4)	16 Sep 2020 21:24:21
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	16 Sep 2020 21:23:54
	(b) (4)	21 Aug 2020 17:35:42

US3732110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 2000'	Lauren Arnett (b) (4)	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	21 Aug 2020 17:35:42

US3732110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4)	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	21 Aug 2020 17:35:42

US3732110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	21 Aug 2020 17:35:42

US3732110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4)	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	21 Aug 2020 17:35:42

US3732110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4)	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	21 Aug 2020 17:35:42

US3732110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:42

US3732110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '2000'	System	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:42

US3732110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:42

US3732110

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Lauren Arnett (b) (4)	21 Aug 2020 17:35:42
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:49

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 15:47:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	20 Oct 2020 15:47:46
Data point term sent to Coder	System	20 Oct 2020 15:46:23
Coding entries removed.	Amara Yilmaz (b) (4)	20 Oct 2020 15:45:41
User entered 'LISINOPRIL drug allergy' reason for change: Data Entry Error	(b) (4)	20 Oct 2020 15:45:41
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Amara Yilmaz (b) (4)	20 Oct 2020 15:45:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	16 Sep 2020 21:26:33
Data point term sent to Coder	Coder Import (b) (4)	16 Sep 2020 21:26:33
User entered 'allergy to lisinopril'	(b) (4)	16 Sep 2020 21:24:43
	System	16 Sep 2020 21:24:38
	Lauren Arnett (b) (4)	16 Sep 2020 21:24:38
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 2000'	Lauren Arnett (b) (4)	16 Sep 2020 21:24:38
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:38

US3732110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	16 Sep 2020 21:24:38
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:38

US3732110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4)	16 Sep 2020 21:24:38
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	16 Sep 2020 21:24:38

US3732110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '2000'	System	16 Sep 2020 21:24:38

US3732110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:24:38

US3732110

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:24:38

US3732110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:49

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 15:47:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	20 Oct 2020 15:47:44
Data point term sent to Coder	System	20 Oct 2020 15:46:24
Coding entries removed.	Amara Yilmaz (b) (4)	20 Oct 2020 15:46:02
User entered 'NAPROXEN drug allergy' reason for change: Data Entry Error	(b) (4)	20 Oct 2020 15:46:02
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Amara Yilmaz (b) (4)	20 Oct 2020 15:46:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	16 Sep 2020 21:26:52
Data point term sent to Coder	Coder Import (b) (4)	16 Sep 2020 21:26:52
User entered 'allergy to naproxen'	System	16 Sep 2020 21:25:44
	Lauren Arnett (b) (4)	16 Sep 2020 21:24:52
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 2000'	Lauren Arnett (b) (4)	16 Sep 2020 21:24:52
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:52

US3732110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:52

US3732110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:52

US3732110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:52

US3732110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	16 Sep 2020 21:24:52

US3732110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '2000'	System	16 Sep 2020 21:24:52

US3732110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:24:52

US3732110

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:24:52

US3732110

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:49

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataract (right) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 19:33:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	18 Sep 2020 19:33:47
Data point term sent to Coder	System	18 Sep 2020 16:39:43
Coding entries removed.	Lauren Arnett (b) (4)	18 Sep 2020 16:38:56
User entered 'CATARACTS - right eye' reason for change: New Information	(b) (4)	
User entered 'CATARACTS - right eye' reason for change: New Information	Lauren Arnett (b) (4)	18 Sep 2020 16:38:56
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 21:26:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	16 Sep 2020 21:26:53
Data point term sent to Coder	System	16 Sep 2020 21:25:44
User entered 'cataracts'	Lauren Arnett (b) (4)	16 Sep 2020 21:25:03
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 2018'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:03

US3732110

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:03

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:03

US3732110

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:03

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:03

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	16 Sep 2020 21:25:03

US3732110

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '2018'	System	16 Sep 2020 21:25:03

US3732110

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:25:03

US3732110

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:25:03

US3732110

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:49

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 21:26:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	16 Sep 2020 21:26:53
Data point term sent to Coder	System	16 Sep 2020 21:25:44
User entered 'hypothyroidism'	Lauren Arnett (b) (4)	16 Sep 2020 21:25:17
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 2000'	Lauren Arnett (b) (4)	16 Sep 2020 21:25:17
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:17

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:17

US3732110

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:17

US3732110

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4)	16 Sep 2020 21:25:17
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	16 Sep 2020 21:25:17

US3732110

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '2000'	System	16 Sep 2020 21:25:17

US3732110

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:25:17

US3732110

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:25:17

US3732110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:12:49

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:26:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:26:54
Data point term sent to Coder	System	16 Sep 2020 21:25:44
User entered 'obesity'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:27

US3732110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 1958'	Lauren Arnett (b) (4)	16 Sep 2020 21:25:27
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4)	16 Sep 2020 21:25:27
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:12:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	16 Sep 2020 21:25:27
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:27

US3732110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:12:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4)	16 Sep 2020 21:25:27
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Jan 1958'	System	16 Sep 2020 21:25:27

US3732110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '1958'	System	16 Sep 2020 21:25:27

US3732110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:25:27

US3732110

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:25:27

US3732110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:12:49

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Skin preneoplastic conditions NEC, PT: Actinic keratosis, LLT: Actinic keratosis - version MedDRA\23.0.	Coder Import (b) (4)	18 Sep 2020 16:41:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	18 Sep 2020 16:41:00
Data point term sent to Coder	System	18 Sep 2020 16:39:43
Coding entries removed.	Lauren Arnett (b) (4)	18 Sep 2020 16:39:29
User entered 'ACTINIC KERATOSIS - scalp' reason for change: New Information	(b) (4)	18 Sep 2020 16:39:29
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Skin preneoplastic conditions NEC, PT: Actinic keratosis, LLT: Actinic keratosis - version MedDRA\23.0.	Lauren Arnett (b) (4)	18 Sep 2020 16:39:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 21:27:40
Data point term sent to Coder	(b) (4)	16 Sep 2020 21:27:40
User entered 'actinic keratosis'	System	16 Sep 2020 21:26:47
	Lauren Arnett (b) (4)	16 Sep 2020 21:26:40
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 1990'	Lauren Arnett (b) (4)	16 Sep 2020 21:26:40
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:26:40

US3732110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:12:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:26:40

US3732110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:26:40

US3732110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:12:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4)	16 Sep 2020 21:26:40
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	16 Sep 2020 21:26:40

US3732110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '1990'	System	16 Sep 2020 21:26:40

US3732110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:26:40

US3732110

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:26:40

US3732110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:12:49

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Vascular disorders, HLG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 21:28:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 21:28:49
Data point term sent to Coder	System	16 Sep 2020 21:27:48
User entered 'hypertension'	Lauren Arnett (b) (4)	16 Sep 2020 21:26:51
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 1995'	Lauren Arnett (b) (4)	16 Sep 2020 21:26:51
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:26:51

US3732110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:12:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:26:51

US3732110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:26:51

US3732110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:12:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4)	16 Sep 2020 21:26:51
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	16 Sep 2020 21:26:51

US3732110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '1995'	System	16 Sep 2020 21:26:51

US3732110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:26:51

US3732110

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:26:51

US3732110

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:12:49

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:28:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:28:48
Data point term sent to Coder	System	16 Sep 2020 21:27:48
User entered 'hyperlipidemia'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:06

US3732110

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 1980'	Lauren Arnett (b) (4)	16 Sep 2020 21:27:06
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:06

US3732110

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:12:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:06

US3732110

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:06

US3732110

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:12:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4)	16 Sep 2020 21:27:06
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	16 Sep 2020 21:27:06

US3732110

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '1980'	System	16 Sep 2020 21:27:06

US3732110

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:27:06

US3732110

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:27:06

US3732110

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:12:49

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:28:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:28:50
Data point term sent to Coder	System	16 Sep 2020 21:27:49
User entered 'atrial fibrillation'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:43

US3732110

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 2000'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:43

US3732110

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:43

US3732110

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:12:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:43

US3732110

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:43

US3732110

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:12:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:43

US3732110

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	16 Sep 2020 21:27:43

US3732110

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '2000'	System	16 Sep 2020 21:27:43

US3732110

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:27:43

US3732110

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:27:43

US3732110

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:12:49

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:30:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:30:54
Data point term sent to Coder	System	16 Sep 2020 21:28:49
User entered 'benign prostatic hypertrophy'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:28:01

US3732110

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 2015'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:28:01

US3732110

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4)	16 Sep 2020 21:28:01
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:12:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:28:01

US3732110

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:28:01

US3732110

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:12:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4)	16 Sep 2020 21:28:01
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	16 Sep 2020 21:28:01

US3732110

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '2015'	System	16 Sep 2020 21:28:01

US3732110

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:28:01

US3732110

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:28:01

US3732110

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:12:49

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Implantable defibrillator insertion, LLT: Implantable cardioverter defibrillator insertion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:31:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:31:41
Data point term sent to Coder	System	16 Sep 2020 21:30:53
User entered 'automatic implantable cardioverter defibrillator'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:19

US3732110

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 2000'	Lauren Arnett (b) (4)	16 Sep 2020 21:30:19
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:19

US3732110

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:12:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:19

US3732110

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:19

US3732110

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:12:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:19

US3732110

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	16 Sep 2020 21:30:19

US3732110

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '2000'	System	16 Sep 2020 21:30:19

US3732110

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:30:19

US3732110

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:30:19

US3732110

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:12:49

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:04:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:04:20
Data point term sent to Coder	System	13 Oct 2020 20:03:58
Coding entries removed.	Amara Yilmaz (b) (4) (b) (4)	13 Oct 2020 20:03:22
User entered 'GOUT Right Big toe' reason for change: New Information	Amara Yilmaz (b) (4) (b) (4)	13 Oct 2020 20:03:22
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:31:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:31:43
Data point term sent to Coder	System	16 Sep 2020 21:30:53
User entered 'gout'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:29

US3732110

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 1990'	Lauren Arnett (b) (4)	16 Sep 2020 21:30:29
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:29

US3732110

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:12:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:29

US3732110

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:29

US3732110

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:12:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4)	16 Sep 2020 21:30:29
	(b) (4)	

US3732110

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	16 Sep 2020 21:30:29

US3732110

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '1990'	System	16 Sep 2020 21:30:29

US3732110

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:30:29

US3732110

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 21:30:29

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:41
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:27

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:43
User entered '20 Aug 2020'	Lauren Arnett (b) (4)	21 Aug 2020 17:37:27
	(b) (4)	

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 05:36:23
User closed query 'Per Source, "Vitals Time = 12:05". Please re-confirm with source and correct.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 05:36:19
Query 'Per Source, "Vitals Time = 12:05". Please re-confirm with source and correct.' answered by data change (Site from CRA).	System	10 Nov 2020 00:56:56
User entered '12:05' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 00:56:56
User opened query 'Per Source, "Vitals Time = 12:05". Please re-confirm with source and correct.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 21:03:45
User entered '12:25'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:27

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:05'	System	10 Nov 2020 00:56:56
User entered '20 Aug 2020 12:25'	System	21 Aug 2020 17:37:27

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:47
User entered '183.0' cm	Lauren Arnett (b) (4)	21 Aug 2020 17:37:27
DataPoint set to visible.	(b) (4) System	20 Aug 2020 20:03:50

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:49
User entered '96.7' kg	Lauren Arnett (b) (4)	21 Aug 2020 17:37:27
DataPoint set to visible.	(b) (4) System	20 Aug 2020 20:03:50

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
Amendment Manager: User entered '28.87515'	System	17 Sep 2020 00:16:51
User entered '28.9'	System	21 Aug 2020 17:37:27
DataPoint set to visible.	System	20 Aug 2020 20:03:50

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	21 Aug 2020 17:37:27
DataPoint set to visible.	System	20 Aug 2020 20:03:50

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:32:42
User entered '98.5' F	Lauren Arnett (b) (4)	21 Aug 2020 17:37:27
	(b) (4)	

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:32:42
User entered 'Oral (Oral)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:27

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:54
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:27

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:32:42
User entered '71'	Lauren Arnett (b) (4)	21 Aug 2020 17:37:27
	(b) (4)	

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Aug 2020 17:37:27

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:32:42
User entered '16'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:27

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Aug 2020 17:37:27

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:32:42
User entered '121'	Lauren Arnett (b) (4)	21 Aug 2020 17:37:27
	(b) (4)	

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 17:37:27

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:56:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:32:42
User entered '70'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:27

US3732110

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 17:37:27

US3732110

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:07:20
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:39

US3732110

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:07:20
User entered '20 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:39

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:10:54
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:10:56
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:10:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:10:58
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:00
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:02
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:04
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:05
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:08
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:09
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:18:00
User closed query 'Per Source, "Other = Yes", Subject is >65 Yrs Old. Please re-review Source and correct. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 06:17:54
Query 'Per Source, "Other = Yes", Subject is >65 Yrs System Old. Please re-review Source and correct. ' answered by data change (Site from CRA).		22 Oct 2020 21:57:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Arnett (b) (4)	22 Oct 2020 21:57:36
User opened query 'Per Source, "Other = Yes", Subject is >65 Yrs Old. Please re-review Source and correct. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 21:08:38
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:18:00
User closed query 'Per Source, "Other = Yes", Subject is >65 Yrs Old. Please re-review Source and correct. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 06:17:57
Query 'Per Source, "Other = Yes", Subject is >65 Yrs System Old. Please re-review Source and correct. ' answered by data change (Site from CRA).		22 Oct 2020 21:57:36
User entered '> 65 years old, can't shelter in place lives in high density housing' reason for change: New Information	Lauren Arnett (b) (4) (b) (4)	22 Oct 2020 21:57:36
User opened query 'Per Source, "Other = Yes", Subject is >65 Yrs Old. Please re-review Source and correct. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 21:10:49
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:14
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:15
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:18
User entered '1'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:20
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:22
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:12:04
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:43

US3732110

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:12:04
User entered '20 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:43

US3732110

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:12:04
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:43

US3732110

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	21 Aug 2020 17:38:43

US3732110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:12:16
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:24:36

US3732110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:12:17
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 06:00:11
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 06:00:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 19:24:36
User entered '187186' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:24:36

US3732110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:12:19
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:24:36

US3732110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:12:21
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 12:58:57
Query 'PER CDM: Please complete this section of the form.' answered with 'complete ' (Site from DM).	Lauren Arnett (b) (4)	15 Sep 2020 00:15:08
User entered 'No (N)'	(b) (4)	
	Lauren Arnett (b) (4)	15 Sep 2020 00:14:59
	(b) (4)	
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:15:35

US3732110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:17:28
User closed query 'Per Medical HX Source; Subject has Hx of Atrial Fib, Implantable Cardio Defibrillator. Please re-confirm if this is considered part of "Significant Cardiac Disease". ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 06:17:26
Query 'Per Medical HX Source; Subject has Hx of Atrial Fib, Implantable Cardio Defibrillator. Please re-confirm if this is considered part of "Significant Cardiac Disease". ' answered with 'updated per subjects medical history' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 19:57:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 19:57:29
User opened query 'Per Medical HX Source; Subject has Hx of Atrial Fib, Implantable Cardio Defibrillator. Please re-confirm if this is considered part of "Significant Cardiac Disease". ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 21:14:18
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 00:14:59

US3732110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:14:20
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 00:14:59

US3732110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:14:22
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 00:14:59

US3732110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:14:24
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 00:14:59

US3732110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:14:25
User entered 'No (N)'	Lauren Arnett (b) (4)	22 Sep 2020 21:52:24
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 10:37:25
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:50:15

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:49

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:53
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 14:12:11
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:31:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:31:15
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 19:14:17
User entered '183.0' cm	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:49

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4)	16 Sep 2020 21:31:15
User entered '96.7' kg	(b) (4)	
	Lauren Arnett (b) (4)	21 Aug 2020 17:39:42
	(b) (4)	

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:49

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:53
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 14:12:11
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:31:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:31:15
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 19:14:17
User entered '183.0' cm	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:49

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4)	16 Sep 2020 21:31:15
User entered '96.7' kg	Lauren Arnett (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:33:50
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '20 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:33:50
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '12:05' reason for change: Data Entry Error	Lauren Arnett (b) (4)	22 Sep 2020 21:53:29
User entered '12:25' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:33:50
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:05'	System	22 Sep 2020 21:53:29
User entered '20 Aug 2020 12:25'	System	29 Aug 2020 21:33:50
User entered empty.	System	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '98.5' F reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:33:50
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:33:50
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '71' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:33:50
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Aug 2020 21:33:50
User entered empty.	System	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:33:50
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Aug 2020 21:33:50
User entered empty.	System	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '121' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:33:50
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 21:33:50
User entered empty.	System	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:33:50
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 21:33:50
User entered empty.	System	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:49

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:53
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 14:12:11
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:31:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:31:15
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 19:14:17
User entered '183.0' cm	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:49

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4)	16 Sep 2020 21:31:15
User entered '96.7' kg	Lauren Arnett (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '20 Aug 2020'	Lauren Arnett (b) (4)	21 Aug 2020 17:39:42
	(b) (4)	

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '13:29'	Lauren Arnett (b) (4)	21 Aug 2020 17:39:42
	(b) (4)	

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 13:29'	System	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '97.5' F	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered 'Oral (Oral)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '70'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '18'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '137'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '67'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 17:39:42

US3732110

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:11
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:51

US3732110

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:11
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:51

US3732110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:24
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:04:27

US3732110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:24
User entered empty.	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:04:27

US3732110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:24
User entered empty.	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:04:27

US3732110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 20:04:27

US3732110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:24
User entered '20 Aug 2020'	Lauren Arnett (b) (4)	20 Aug 2020 20:04:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:24
User entered '12:59'	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:04:27

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:24
User entered 'Left Arm (LEFT ARM)'	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:04:27

US3732110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:24
User entered 'ONCE'	System	20 Aug 2020 20:04:27

US3732110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 20:04:27

US3732110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:35
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:11

US3732110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:35
User entered '20 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:11

US3732110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:35
User entered '12:32'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:11

US3732110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:32'	System	21 Aug 2020 17:40:11

US3732110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:12:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:56
User entered '20 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:26

US3732110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:49

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Arnett (b) (4)	21 Aug 2020 17:40:26

US3732110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:56
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:26

US3732110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:56
User entered '12:49'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:26

US3732110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:49'	System	21 Aug 2020 17:40:26

US3732110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:49

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Arnett (b) (4)	21 Aug 2020 17:40:26

US3732110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:56
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:26

US3732110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:56
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 17:40:26
	(b) (4)	

US3732110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 17:40:26

US3732110

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:23:04
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:31

US3732110

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:40:31

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:31:50', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '966ccd7d-c457-4b68-887b-eea81a8d31c3'	System	20 Aug 2020 20:32:24
User entered 'Yes (Y)'	System	20 Aug 2020 20:32:24

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:32:03', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '966ccd7d-c457-4b68-887b-eea81a8d31c3'	System	20 Aug 2020 20:32:24
User entered '97.5'	System	20 Aug 2020 20:32:24

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:32:11', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '966ccd7d-c457-4b68-887b-eea81a8d31c3'	System	20 Aug 2020 20:32:24
User entered 'No (N)'	System	20 Aug 2020 20:32:24

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:32:21', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '966ccd7d-c457-4b68-887b-eea81a8d31c3' User entered '20 Aug 2020 13:32'	System	20 Aug 2020 20:32:24
	System	20 Aug 2020 20:32:24

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 13:19'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 15:49'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:11:17', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '295be918-d8cb-4013-8ed8-310dcec094be'	System	21 Aug 2020 15:11:54
User entered 'Yes (Y)'	System	21 Aug 2020 15:11:54

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:11:26', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '295be918-d8cb-4013-8ed8-310dcec094be'	System	21 Aug 2020 15:11:54
User entered '95.1'	System	21 Aug 2020 15:11:54

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:11:33', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '295be918-d8cb-4013-8ed8-310dcec094be'	System	21 Aug 2020 15:11:54
User entered 'No (N)'	System	21 Aug 2020 15:11:54

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:11:50', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '295be918-d8cb-4013-8ed8-310dcec094be'	System	21 Aug 2020 15:11:54
User entered '21 Aug 2020 08:11'	System	21 Aug 2020 15:11:54

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 16:44'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 2'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:44:03', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e1aaa283-3f80-4f92-9089-ae154844c7fb'	System	22 Aug 2020 16:44:29
User entered 'Yes (Y)'	System	22 Aug 2020 16:44:29

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:44:14', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e1aaa283-3f80-4f92-9089-ae154844c7fb'	System	22 Aug 2020 16:44:29
User entered '96.8'	System	22 Aug 2020 16:44:29

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:44:18', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e1aaa283-3f80-4f92-9089-ae154844c7fb'	System	22 Aug 2020 16:44:29
User entered 'No (N)'	System	22 Aug 2020 16:44:29

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:44:26', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e1aaa283-3f80-4f92-9089-ae154844c7fb'	System	22 Aug 2020 16:44:29
User entered '22 Aug 2020 09:44'	System	22 Aug 2020 16:44:29

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 3'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:33:17', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '05e440d3-8052-4a2e-b491-28df9ebae56a'	System	23 Aug 2020 15:33:44
User entered 'Yes (Y)'	System	23 Aug 2020 15:33:44

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:33:29', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '05e440d3-8052-4a2e-b491-28df9ebae56a'	System	23 Aug 2020 15:33:44
User entered '97.6'	System	23 Aug 2020 15:33:44

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:33:35', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '05e440d3-8052-4a2e-b491-28df9ebae56a'	System	23 Aug 2020 15:33:44
User entered 'No (N)'	System	23 Aug 2020 15:33:44

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:33:42', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '05e440d3-8052-4a2e-b491-28df9ebae56a' User entered '23 Aug 2020 08:33'	System	23 Aug 2020 15:33:44
	System	23 Aug 2020 15:33:44

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 4'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 5'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 6'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:50:52', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3f754df3-2fe0-43f3-bd00-237d8eeb9848'	System	26 Aug 2020 03:51:14
User entered 'Yes (Y)'	System	26 Aug 2020 03:51:14

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:51:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3f754df3-2fe0-43f3-bd00-237d8eeb9848'	System	26 Aug 2020 03:51:14
User entered '96.8'	System	26 Aug 2020 03:51:14

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:51:05', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3f754df3-2fe0-43f3-bd00-237d8eeb9848'	System	26 Aug 2020 03:51:14
User entered 'No (N)'	System	26 Aug 2020 03:51:14

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:51:12', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3f754df3-2fe0-43f3-bd00-237d8eeb9848'	System	26 Aug 2020 03:51:14
User entered '25 Aug 2020 20:51'	System	26 Aug 2020 03:51:14

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 7'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:00:50', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '8ddbe6f1-32e1-41f0-9bdc-a788282becef'	System	27 Aug 2020 18:01:12
User entered 'Yes (Y)'	System	27 Aug 2020 18:01:12

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:01', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '8ddbe6f1-32e1-41f0-9bdc-a788282becef'	System	27 Aug 2020 18:01:12
User entered '96.8'	System	27 Aug 2020 18:01:12

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:05', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '8ddbe6f1-32e1-41f0-9bdc-a788282becef'	System	27 Aug 2020 18:01:12
User entered 'No (N)'	System	27 Aug 2020 18:01:12

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:11', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '8ddbe6f1-32e1-41f0-9bdc-a788282becef'	System	27 Aug 2020 18:01:12
User entered '27 Aug 2020 11:01'	System	27 Aug 2020 18:01:12

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:32:39', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2ccf9171-8f97-4975-9c30-64b6a0c3d97a'	System	20 Aug 2020 20:34:49
User entered 'Does not interfere with activity (2)'	System	20 Aug 2020 20:34:49

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:32:52', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2ccf9171-8f97-4975-9c30-64b6a0c3d97a'	System	20 Aug 2020 20:34:49
User entered 'No (N)'	System	20 Aug 2020 20:34:49

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:34:14', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2ccf9171-8f97-4975-9c30-64b6a0c3d97a'	System	20 Aug 2020 20:34:49
User entered 'No (N)'	System	20 Aug 2020 20:34:49

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:34:29', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2ccf9171-8f97-4975-9c30-64b6a0c3d97a'	System	20 Aug 2020 20:34:49
User entered 'None (1)'	System	20 Aug 2020 20:34:49

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:34:44', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2ccf9171-8f97-4975-9c30-64b6a0c3d97a' User entered '20 Aug 2020 13:34'	System	20 Aug 2020 20:34:49
	System	20 Aug 2020 20:34:49

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 13:19'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 15:49'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:12:23', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3337e0ea-dd6a-4af4-a9e9-173a0f3483b7'	System	21 Aug 2020 15:14:12
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 15:14:12

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:12:28', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3337e0ea-dd6a-4af4-a9e9-173a0f3483b7'	System	21 Aug 2020 15:14:12
User entered 'No (N)'	System	21 Aug 2020 15:14:12

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:13:46', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3337e0ea-dd6a-4af4-a9e9-173a0f3483b7'	System	21 Aug 2020 15:14:12
User entered 'No (N)'	System	21 Aug 2020 15:14:12

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3337e0ea-dd6a-4af4-a9e9-173a0f3483b7'	System	21 Aug 2020 15:14:12
User entered 'None (1)'	System	21 Aug 2020 15:14:12

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:09', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3337e0ea-dd6a-4af4-a9e9-173a0f3483b7'	System	21 Aug 2020 15:14:12
User entered '21 Aug 2020 08:14'	System	21 Aug 2020 15:14:12

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 16:44'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 2'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:44:38', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '90c4244f-2a63-4603-8702-41ed3bf34793'	System	22 Aug 2020 16:44:57
User entered 'None (1)'	System	22 Aug 2020 16:44:57

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:44:42', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '90c4244f-2a63-4603-8702-41ed3bf34793'	System	22 Aug 2020 16:44:57
User entered 'No (N)'	System	22 Aug 2020 16:44:57

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:44:46', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '90c4244f-2a63-4603-8702-41ed3bf34793'	System	22 Aug 2020 16:44:57
User entered 'No (N)'	System	22 Aug 2020 16:44:57

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:44:51', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '90c4244f-2a63-4603-8702-41ed3bf34793'	System	22 Aug 2020 16:44:57
User entered 'None (1)'	System	22 Aug 2020 16:44:57

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:44:56', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '90c4244f-2a63-4603-8702-41ed3bf34793'	System	22 Aug 2020 16:44:57
User entered '22 Aug 2020 09:44'	System	22 Aug 2020 16:44:57

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 3'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:33:52', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4d9d809f-d9db-494b-afb7-7ec23954ab15'	System	23 Aug 2020 15:34:13
User entered 'None (1)'	System	23 Aug 2020 15:34:13

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:33:57', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4d9d809f-d9db-494b-afb7-7ec23954ab15'	System	23 Aug 2020 15:34:13
User entered 'No (N)'	System	23 Aug 2020 15:34:13

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:01', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4d9d809f-d9db-494b-afb7-7ec23954ab15'	System	23 Aug 2020 15:34:13
User entered 'No (N)'	System	23 Aug 2020 15:34:13

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:05', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4d9d809f-d9db-494b-afb7-7ec23954ab15'	System	23 Aug 2020 15:34:13
User entered 'None (1)'	System	23 Aug 2020 15:34:13

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:12', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4d9d809f-d9db-494b-afb7-7ec23954ab15'	System	23 Aug 2020 15:34:13
User entered '23 Aug 2020 08:34'	System	23 Aug 2020 15:34:13

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 4'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 5'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 6'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:51:25', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '601d2b53-2742-4d31-b31b-3d49f227aa9e'	System	26 Aug 2020 03:51:49
User entered 'None (1)'	System	26 Aug 2020 03:51:49

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:51:31', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '601d2b53-2742-4d31-b31b-3d49f227aa9e'	System	26 Aug 2020 03:51:49
User entered 'No (N)'	System	26 Aug 2020 03:51:49

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:51:36', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '601d2b53-2742-4d31-b31b-3d49f227aa9e'	System	26 Aug 2020 03:51:49
User entered 'No (N)'	System	26 Aug 2020 03:51:49

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:51:41', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '601d2b53-2742-4d31-b31b-3d49f227aa9e'	System	26 Aug 2020 03:51:49
User entered 'None (1)'	System	26 Aug 2020 03:51:49

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:51:48', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '601d2b53-2742-4d31-b31b-3d49f227aa9e'	System	26 Aug 2020 03:51:49
User entered '25 Aug 2020 20:51'	System	26 Aug 2020 03:51:49

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 7'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:20', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'db77d839-2e02-421e-96d0-13855e0100dc'	System	27 Aug 2020 18:01:39
User entered 'None (1)'	System	27 Aug 2020 18:01:39

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:24', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'db77d839-2e02-421e-96d0-13855e0100dc'	System	27 Aug 2020 18:01:39
User entered 'No (N)'	System	27 Aug 2020 18:01:39

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:27', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'db77d839-2e02-421e-96d0-13855e0100dc'	System	27 Aug 2020 18:01:39
User entered 'No (N)'	System	27 Aug 2020 18:01:39

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:32', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'db77d839-2e02-421e-96d0-13855e0100dc'	System	27 Aug 2020 18:01:39
User entered 'None (1)'	System	27 Aug 2020 18:01:39

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:36', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'db77d839-2e02-421e-96d0-13855e0100dc'	System	27 Aug 2020 18:01:39
User entered '27 Aug 2020 11:01'	System	27 Aug 2020 18:01:39

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:34:52', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '27eee2b4-8662-4458-853f-c7ee910d27a4'	System	20 Aug 2020 20:35:28
User entered 'None (0)'	System	20 Aug 2020 20:35:28

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:34:56', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '27eee2b4-8662-4458-853f-c7ee910d27a4'	System	20 Aug 2020 20:35:28
User entered 'None (0)'	System	20 Aug 2020 20:35:28

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:35:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '27eee2b4-8662-4458-853f-c7ee910d27a4'	System	20 Aug 2020 20:35:28
User entered 'None (0)'	System	20 Aug 2020 20:35:28

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:35:03', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '27eee2b4-8662-4458-853f-c7ee910d27a4'	System	20 Aug 2020 20:35:28
User entered 'None (0)'	System	20 Aug 2020 20:35:28

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:35:06', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '27eee2b4-8662-4458-853f-c7ee910d27a4'	System	20 Aug 2020 20:35:28
User entered 'None (0)'	System	20 Aug 2020 20:35:28

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:35:10', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '27eee2b4-8662-4458-853f-c7ee910d27a4'	System	20 Aug 2020 20:35:28
User entered 'None (0)'	System	20 Aug 2020 20:35:28

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:35:15', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '27eee2b4-8662-4458-853f-c7ee910d27a4'	System	20 Aug 2020 20:35:28
User entered 'No (N)'	System	20 Aug 2020 20:35:28

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:35:25', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '27eee2b4-8662-4458-853f-c7ee910d27a4'	System	20 Aug 2020 20:35:28
User entered '20 Aug 2020 13:35'	System	20 Aug 2020 20:35:28

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 13:19'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 15:49'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:22', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '45861f7b-e0d1-48d9-a4a8-468ea861baa0'	System	21 Aug 2020 15:14:55
User entered 'None (0)'	System	21 Aug 2020 15:14:55

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:25', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '45861f7b-e0d1-48d9-a4a8-468ea861baa0'	System	21 Aug 2020 15:14:55
User entered 'None (0)'	System	21 Aug 2020 15:14:55

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:29', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '45861f7b-e0d1-48d9-a4a8-468ea861baa0'	System	21 Aug 2020 15:14:55
User entered 'None (0)'	System	21 Aug 2020 15:14:55

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:33', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '45861f7b-e0d1-48d9-a4a8-468ea861baa0' User entered 'None (0)'	System	21 Aug 2020 15:14:55
	System	21 Aug 2020 15:14:55

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:36', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '45861f7b-e0d1-48d9-a4a8-468ea861baa0'	System	21 Aug 2020 15:14:55
User entered 'None (0)'	System	21 Aug 2020 15:14:55

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:39', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '45861f7b-e0d1-48d9-a4a8-468ea861baa0'	System	21 Aug 2020 15:14:55
User entered 'None (0)'	System	21 Aug 2020 15:14:55

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:48', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '45861f7b-e0d1-48d9-a4a8-468ea861baa0'	System	21 Aug 2020 15:14:55
User entered 'No (N)'	System	21 Aug 2020 15:14:55

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:52', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '45861f7b-e0d1-48d9-a4a8-468ea861baa0'	System	21 Aug 2020 15:14:55
User entered '21 Aug 2020 08:14'	System	21 Aug 2020 15:14:55

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 16:44'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 2'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:45:05', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a48f542d-f3df-4f30-b03d-115554221092'	System	22 Aug 2020 16:45:50
User entered 'None (0)'	System	22 Aug 2020 16:45:50

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:45:09', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a48f542d-f3df-4f30-b03d-115554221092'	System	22 Aug 2020 16:45:50
User entered 'None (0)'	System	22 Aug 2020 16:45:50

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:45:14', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a48f542d-f3df-4f30-b03d-115554221092'	System	22 Aug 2020 16:45:50
User entered 'None (0)'	System	22 Aug 2020 16:45:50

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:45:23', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a48f542d-f3df-4f30-b03d-115554221092'	System	22 Aug 2020 16:45:50
User entered 'None (0)'	System	22 Aug 2020 16:45:50

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:45:27', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a48f542d-f3df-4f30-b03d-115554221092'	System	22 Aug 2020 16:45:50
User entered 'None (0)'	System	22 Aug 2020 16:45:50

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:45:31', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a48f542d-f3df-4f30-b03d-115554221092'	System	22 Aug 2020 16:45:50
User entered 'None (0)'	System	22 Aug 2020 16:45:50

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:45:36', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a48f542d-f3df-4f30-b03d-115554221092'	System	22 Aug 2020 16:45:50
User entered 'No (N)'	System	22 Aug 2020 16:45:50

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:45:47', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a48f542d-f3df-4f30-b03d-115554221092'	System	22 Aug 2020 16:45:50
User entered '22 Aug 2020 09:45'	System	22 Aug 2020 16:45:50

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 3'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:26', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'eed3342d-906b-43a0-a823-92b9363ff4e2'	System	23 Aug 2020 15:34:55
User entered 'None (0)'	System	23 Aug 2020 15:34:55

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:30', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'eed3342d-906b-43a0-a823-92b9363ff4e2'	System	23 Aug 2020 15:34:55
User entered 'None (0)'	System	23 Aug 2020 15:34:55

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:34', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'eed3342d-906b-43a0-a823-92b9363ff4e2'	System	23 Aug 2020 15:34:55
User entered 'None (0)'	System	23 Aug 2020 15:34:55

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:38', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'eed3342d-906b-43a0-a823-92b9363ff4e2'	System	23 Aug 2020 15:34:55
User entered 'None (0)'	System	23 Aug 2020 15:34:55

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:41', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'eed3342d-906b-43a0-a823-92b9363ff4e2'	System	23 Aug 2020 15:34:55
User entered 'None (0)'	System	23 Aug 2020 15:34:55

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:45', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'eed3342d-906b-43a0-a823-92b9363ff4e2'	System	23 Aug 2020 15:34:55
User entered 'None (0)'	System	23 Aug 2020 15:34:55

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:49', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'eed3342d-906b-43a0-a823-92b9363ff4e2'	System	23 Aug 2020 15:34:55
User entered 'No (N)'	System	23 Aug 2020 15:34:55

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:53', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'eed3342d-906b-43a0-a823-92b9363ff4e2' User entered '23 Aug 2020 08:34'	System	23 Aug 2020 15:34:55
	System	23 Aug 2020 15:34:55

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 4'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 5'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 6'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:51:56', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '043a1911-8c90-4164-a7e6-242080594180'	System	26 Aug 2020 03:52:33
User entered 'None (0)'	System	26 Aug 2020 03:52:33

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:52:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '043a1911-8c90-4164-a7e6-242080594180'	System	26 Aug 2020 03:52:33
User entered 'None (0)'	System	26 Aug 2020 03:52:33

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:52:04', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '043a1911-8c90-4164-a7e6-242080594180'	System	26 Aug 2020 03:52:33
User entered 'None (0)'	System	26 Aug 2020 03:52:33

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:52:09', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '043a1911-8c90-4164-a7e6-242080594180'	System	26 Aug 2020 03:52:33
User entered 'None (0)'	System	26 Aug 2020 03:52:33

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:52:13', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '043a1911-8c90-4164-a7e6-242080594180'	System	26 Aug 2020 03:52:33
User entered 'None (0)'	System	26 Aug 2020 03:52:33

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:52:16', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '043a1911-8c90-4164-a7e6-242080594180'	System	26 Aug 2020 03:52:33
User entered 'None (0)'	System	26 Aug 2020 03:52:33

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:52:21', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '043a1911-8c90-4164-a7e6-242080594180'	System	26 Aug 2020 03:52:33
User entered 'No (N)'	System	26 Aug 2020 03:52:33

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:52:31', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '043a1911-8c90-4164-a7e6-242080594180'	System	26 Aug 2020 03:52:33
User entered '25 Aug 2020 20:52'	System	26 Aug 2020 03:52:33

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 7'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:43', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'f84a2122-15b6-44a1-93bd-6eb20aec32b2'	System	27 Aug 2020 18:02:13
User entered 'None (0)'	System	27 Aug 2020 18:02:13

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:46', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'f84a2122-15b6-44a1-93bd-6eb20aec32b2'	System	27 Aug 2020 18:02:13
User entered 'None (0)'	System	27 Aug 2020 18:02:13

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:50', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'f84a2122-15b6-44a1-93bd-6eb20aec32b2'	System	27 Aug 2020 18:02:13
User entered 'None (0)'	System	27 Aug 2020 18:02:13

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:54', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'f84a2122-15b6-44a1-93bd-6eb20aec32b2'	System	27 Aug 2020 18:02:13
User entered 'None (0)'	System	27 Aug 2020 18:02:13

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:58', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'f84a2122-15b6-44a1-93bd-6eb20aec32b2'	System	27 Aug 2020 18:02:13
User entered 'None (0)'	System	27 Aug 2020 18:02:13

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:02:03', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'f84a2122-15b6-44a1-93bd-6eb20aec32b2'	System	27 Aug 2020 18:02:13
User entered 'None (0)'	System	27 Aug 2020 18:02:13

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:02:07', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'f84a2122-15b6-44a1-93bd-6eb20aec32b2'	System	27 Aug 2020 18:02:13
User entered 'No (N)'	System	27 Aug 2020 18:02:13

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:02:10', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'f84a2122-15b6-44a1-93bd-6eb20aec32b2'	System	27 Aug 2020 18:02:13
User entered '27 Aug 2020 11:02'	System	27 Aug 2020 18:02:13

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

US3732110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:04:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 21:37:50

US3732110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:04:40
User entered '27 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 21:37:50

US3732110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:04:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Aug 2020 21:37:50

US3732110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:04:40
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 21:37:50

US3732110

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:04:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 21:38:15

US3732110

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 21:38:15

US3732110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:05:13
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	03 Sep 2020 18:07:10

US3732110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:05:13
User entered '03 Sep 2020'	Linda Vega (b) (4) (b) (4)	03 Sep 2020 18:07:10

US3732110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:05:13
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	03 Sep 2020 18:07:10

US3732110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:05:13
User entered empty.	Linda Vega (b) (4) (b) (4)	03 Sep 2020 18:07:10

US3732110

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:05:19
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	03 Sep 2020 18:07:14

US3732110

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 18:07:14

US3732110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:10:59
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	10 Sep 2020 22:43:32

US3732110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:10:59
User entered '10 Sep 2020'	Linda Vega (b) (4)	10 Sep 2020 22:43:32
	(b) (4)	

US3732110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:10:59
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	10 Sep 2020 22:43:32

US3732110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:10:59
User entered empty.	Linda Vega (b) (4) (b) (4)	10 Sep 2020 22:43:32

US3732110

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:11:06
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	10 Sep 2020 22:43:35

US3732110

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 22:43:35

US3732110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:11:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:41:31

US3732110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:11:57
User entered '17 Sep 2020'	Lauren Arnett (b) (4)	18 Sep 2020 16:41:31
	(b) (4)	

US3732110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:11:57
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	18 Sep 2020 16:41:31
	(b) (4)	

US3732110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	18 Sep 2020 16:41:31

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '17 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '10:25'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '17 Sep 2020 10:25'	System	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '97.8' F	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered 'Oral (Oral)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered empty.	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '70'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '16'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '95'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 19:07:16
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'abnormal, NCS per investigator assessment ' (Site from System).	Amara Yilmaz (b) (4)	13 Oct 2020 20:06:24
User entered '55' reason for change: Data Entry Error	(b) (4)	18 Sep 2020 16:43:05
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		18 Sep 2020 16:42:57
User entered '58'	Lauren Arnett (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '17 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '11:33'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:33'	System	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '97.8' F	Lauren Arnett (b) (4)	18 Sep 2020 16:42:57
	(b) (4)	

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered 'Oral (Oral)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered empty.	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '70'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '16'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '118'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '65'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 16:42:57

US3732110

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:58
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:15

US3732110

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:58
User entered '17 Sep 2020'	Lauren Arnett (b) (4)	18 Sep 2020 16:43:15
	(b) (4)	

US3732110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:25
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	17 Sep 2020 18:04:56

US3732110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:25
User entered empty.	Lauren Arnett (b) (4) (b) (4)	17 Sep 2020 18:04:56

US3732110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:25
User entered empty.	Lauren Arnett (b) (4) (b) (4)	17 Sep 2020 18:04:56

US3732110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 18:04:56

US3732110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:25
User entered '17 Sep 2020'	Lauren Arnett (b) (4)	17 Sep 2020 18:04:56
	(b) (4)	

US3732110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:25
User entered '11:03'	Lauren Arnett (b) (4)	17 Sep 2020 18:04:56
	(b) (4)	

US3732110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:03'	System	17 Sep 2020 18:04:56

US3732110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:25
User entered 'Left Arm (LEFT ARM)'	Lauren Arnett (b) (4) (b) (4)	17 Sep 2020 18:04:56

US3732110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:25
User entered 'ONCE'	System	17 Sep 2020 18:04:56

US3732110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 18:04:56

US3732110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:47
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:25

US3732110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:47
User entered '17 Sep 2020'	Lauren Arnett (b) (4)	18 Sep 2020 16:43:25
	(b) (4)	

US3732110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:47
User entered '10:38'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:25

US3732110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '17 Sep 2020 10:38'	System	18 Sep 2020 16:43:25

US3732110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:12:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:56
User entered '17 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:38

US3732110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:49

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Arnett (b) (4)	18 Sep 2020 16:43:38

US3732110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:56
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:38

US3732110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:56
User entered '10:30'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:38

US3732110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '17 Sep 2020 10:30'	System	18 Sep 2020 16:43:38

US3732110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:49

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Arnett (b) (4)	18 Sep 2020 16:43:38

US3732110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:56
User entered 'No (N)' reason for change: Data Entry Error	Lauren Arnett (b) (4)	18 Sep 2020 16:43:43
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	18 Sep 2020 16:43:38

US3732110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:56
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	18 Sep 2020 16:43:43
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	18 Sep 2020 16:43:43
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	18 Sep 2020 16:43:38
User entered empty.	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:38

US3732110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:43:38

US3732110

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:15:09
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:48

US3732110

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:43:48

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:42:42', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '00a2a04e-512d-43fd-80fe-413e21bdbee2'	System	17 Sep 2020 18:43:08
User entered 'Yes (Y)'	System	17 Sep 2020 18:43:08

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:42:52', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '00a2a04e-512d-43fd-80fe-413e21bdbee2'	System	17 Sep 2020 18:43:08
User entered '97.8'	System	17 Sep 2020 18:43:08

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:42:58', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '00a2a04e-512d-43fd-80fe-413e21bdbbee2'	System	17 Sep 2020 18:43:08
User entered 'No (N)'	System	17 Sep 2020 18:43:08

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:43:05', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '00a2a04e-512d-43fd-80fe-413e21bdbbee2'	System	17 Sep 2020 18:43:08
User entered '17 Sep 2020 11:43'	System	17 Sep 2020 18:43:08

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:23'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 13:53'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:09:35', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2c792a24-1db9-4d9e-83ab-2addf922225c'	System	18 Sep 2020 17:10:17
User entered 'Yes (Y)'	System	18 Sep 2020 17:10:17

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:09:45', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2c792a24-1db9-4d9e-83ab-2addf922225c'	System	18 Sep 2020 17:10:17
User entered '95.5'	System	18 Sep 2020 17:10:17

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:10:01', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2c792a24-1db9-4d9e-83ab-2addf922225c'	System	18 Sep 2020 17:10:17
User entered 'No (N)'	System	18 Sep 2020 17:10:17

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:10:13', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2c792a24-1db9-4d9e-83ab-2addf922225c'	System	18 Sep 2020 17:10:17
User entered '18 Sep 2020 10:10'	System	18 Sep 2020 17:10:17

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 14:48'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 2'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:22:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e8bc7d3b-0c81-4d56-953f-0ee38d7d192d'	System	19 Sep 2020 17:22:28
User entered 'Yes (Y)'	System	19 Sep 2020 17:22:28

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:22:13', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e8bc7d3b-0c81-4d56-953f-0ee38d7d192d' User entered '97.6'	System	19 Sep 2020 17:22:28
	System	19 Sep 2020 17:22:28

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:22:19', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e8bc7d3b-0c81-4d56-953f-0ee38d7d192d'	System	19 Sep 2020 17:22:28
User entered 'No (N)'	System	19 Sep 2020 17:22:28

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:22:25', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e8bc7d3b-0c81-4d56-953f-0ee38d7d192d' User entered '19 Sep 2020 10:22'	System	19 Sep 2020 17:22:28
	System	19 Sep 2020 17:22:28

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 3'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:08:21', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '18e6ca0c-bcd6-40c0-8555-9ea2128122ca' User entered 'Yes (Y)'	System	20 Sep 2020 03:08:44
	System	20 Sep 2020 03:08:44

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:08:30', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '18e6ca0c-bcd6-40c0-8555-9ea2128122ca' User entered '97.4'	System	20 Sep 2020 03:08:44
	System	20 Sep 2020 03:08:44

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:08:35', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '18e6ca0c-bcd6-40c0-8555-9ea2128122ca' User entered 'No (N)'	System	20 Sep 2020 03:08:44

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:08:41', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '18e6ca0c-bcd6-40c0-8555-9ea2128122ca' User entered '19 Sep 2020 20:08'	System	20 Sep 2020 03:08:44
	System	20 Sep 2020 03:08:44

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 4'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:56:24', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '49b5bef1-370f-4da9-ad10-51fd89cdfc25'	System	21 Sep 2020 04:56:51
User entered 'Yes (Y)'	System	21 Sep 2020 04:56:51

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:56:32', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '49b5bef1-370f-4da9-ad10-51fd89cdfc25'	System	21 Sep 2020 04:56:51
User entered '96.9'	System	21 Sep 2020 04:56:51

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:56:39', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '49b5bef1-370f-4da9-ad10-51fd89cdfc25'	System	21 Sep 2020 04:56:51
User entered 'No (N)'	System	21 Sep 2020 04:56:51

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:56:49', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '49b5bef1-370f-4da9-ad10-51fd89cdfc25'	System	21 Sep 2020 04:56:51
User entered '20 Sep 2020 21:56'	System	21 Sep 2020 04:56:51

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 5'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:09', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2329f0e3-f3f0-4a62-b7c1-54836252e435'	System	21 Sep 2020 20:11:29
User entered 'Yes (Y)'	System	21 Sep 2020 20:11:29

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:16', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2329f0e3-f3f0-4a62-b7c1-54836252e435'	System	21 Sep 2020 20:11:29
User entered '96.0'	System	21 Sep 2020 20:11:29

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:22', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2329f0e3-f3f0-4a62-b7c1-54836252e435'	System	21 Sep 2020 20:11:29
User entered 'No (N)'	System	21 Sep 2020 20:11:29

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:26', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2329f0e3-f3f0-4a62-b7c1-54836252e435'	System	21 Sep 2020 20:11:29
User entered '21 Sep 2020 13:11'	System	21 Sep 2020 20:11:29

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 6'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:04', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'd1919c64-7be8-4107-b666-2be76a3ed9dd'	System	23 Sep 2020 04:04:26
User entered 'Yes (Y)'	System	23 Sep 2020 04:04:26

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:10', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'd1919c64-7be8-4107-b666-2be76a3ed9dd'	System	23 Sep 2020 04:04:26
User entered '96.3'	System	23 Sep 2020 04:04:26

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:15', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'd1919c64-7be8-4107-b666-2be76a3ed9dd'	System	23 Sep 2020 04:04:26
User entered 'No (N)'	System	23 Sep 2020 04:04:26

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:22', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'd1919c64-7be8-4107-b666-2be76a3ed9dd'	System	23 Sep 2020 04:04:26
User entered '22 Sep 2020 21:04'	System	23 Sep 2020 04:04:26

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 7'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:43:24', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '38f46d18-6170-43f0-885b-c415a50ecf1f'	System	17 Sep 2020 18:44:07
User entered 'None (1)'	System	17 Sep 2020 18:44:07

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:43:37', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '38f46d18-6170-43f0-885b-c415a50ecf1f'	System	17 Sep 2020 18:44:07
User entered 'No (N)'	System	17 Sep 2020 18:44:07

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:43:47', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '38f46d18-6170-43f0-885b-c415a50ecf1f'	System	17 Sep 2020 18:44:07
User entered 'No (N)'	System	17 Sep 2020 18:44:07

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '38f46d18-6170-43f0-885b-c415a50ecf1f'	System	17 Sep 2020 18:44:07
User entered 'None (1)'	System	17 Sep 2020 18:44:07

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:05', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '38f46d18-6170-43f0-885b-c415a50ecf1f' User entered '17 Sep 2020 11:44'	System	17 Sep 2020 18:44:07
	System	17 Sep 2020 18:44:07

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:23'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 13:53'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:10:24', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e39e84f2-74ac-4fc6-a435-109e325fa9ce'	System	18 Sep 2020 17:11:26
User entered 'None (1)'	System	18 Sep 2020 17:11:26

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:02', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e39e84f2-74ac-4fc6-a435-109e325fa9ce'	System	18 Sep 2020 17:11:26
User entered 'No (N)'	System	18 Sep 2020 17:11:26

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:07', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e39e84f2-74ac-4fc6-a435-109e325fa9ce'	System	18 Sep 2020 17:11:26
User entered 'No (N)'	System	18 Sep 2020 17:11:26

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:17', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e39e84f2-74ac-4fc6-a435-109e325fa9ce'	System	18 Sep 2020 17:11:26
User entered 'None (1)'	System	18 Sep 2020 17:11:26

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:25', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e39e84f2-74ac-4fc6-a435-109e325fa9ce' User entered '18 Sep 2020 10:11'	System	18 Sep 2020 17:11:26
	System	18 Sep 2020 17:11:26

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 14:48'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 2'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:22:36', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '00477942-1adc-4e1e-85c3-39c1801d1cc2'	System	19 Sep 2020 17:23:08
User entered 'None (1)'	System	19 Sep 2020 17:23:08

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:22:42', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '00477942-1adc-4e1e-85c3-39c1801d1cc2'	System	19 Sep 2020 17:23:08
User entered 'No (N)'	System	19 Sep 2020 17:23:08

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:22:46', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '00477942-1adc-4e1e-85c3-39c1801d1cc2'	System	19 Sep 2020 17:23:08
User entered 'No (N)'	System	19 Sep 2020 17:23:08

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:01', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '00477942-1adc-4e1e-85c3-39c1801d1cc2'	System	19 Sep 2020 17:23:08
User entered 'None (1)'	System	19 Sep 2020 17:23:08

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:06', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '00477942-1adc-4e1e-85c3-39c1801d1cc2'	System	19 Sep 2020 17:23:08
User entered '19 Sep 2020 10:23'	System	19 Sep 2020 17:23:08

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 3'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:08:50', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '5e806739-0e29-4bf8-8df7-0a8d71c1c0d2'	System	20 Sep 2020 03:09:25
User entered 'None (1)'	System	20 Sep 2020 03:09:25

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:03', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '5e806739-0e29-4bf8-8df7-0a8d71c1c0d2'	System	20 Sep 2020 03:09:25
User entered 'No (N)'	System	20 Sep 2020 03:09:25

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:07', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '5e806739-0e29-4bf8-8df7-0a8d71c1c0d2'	System	20 Sep 2020 03:09:25
User entered 'No (N)'	System	20 Sep 2020 03:09:25

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:20', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '5e806739-0e29-4bf8-8df7-0a8d71c1c0d2'	System	20 Sep 2020 03:09:25
User entered 'None (1)'	System	20 Sep 2020 03:09:25

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:24', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '5e806739-0e29-4bf8-8df7-0a8d71c1c0d2'	System	20 Sep 2020 03:09:25
User entered '19 Sep 2020 20:09'	System	20 Sep 2020 03:09:25

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 4'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:56:57', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '408d13f8-70b2-48d9-b354-8b76347f5135'	System	21 Sep 2020 04:57:18
User entered 'None (1)'	System	21 Sep 2020 04:57:18

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:01', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '408d13f8-70b2-48d9-b354-8b76347f5135'	System	21 Sep 2020 04:57:18
User entered 'No (N)'	System	21 Sep 2020 04:57:18

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:07', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '408d13f8-70b2-48d9-b354-8b76347f5135'	System	21 Sep 2020 04:57:18
User entered 'No (N)'	System	21 Sep 2020 04:57:18

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:11', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '408d13f8-70b2-48d9-b354-8b76347f5135'	System	21 Sep 2020 04:57:18
User entered 'None (1)'	System	21 Sep 2020 04:57:18

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:15', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '408d13f8-70b2-48d9-b354-8b76347f5135'	System	21 Sep 2020 04:57:18
User entered '20 Sep 2020 21:57'	System	21 Sep 2020 04:57:18

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 5'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:33', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4f38f475-a3aa-427e-898e-720c8f944c55'	System	21 Sep 2020 20:11:49
User entered 'None (1)'	System	21 Sep 2020 20:11:49

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:37', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4f38f475-a3aa-427e-898e-720c8f944c55'	System	21 Sep 2020 20:11:49
User entered 'No (N)'	System	21 Sep 2020 20:11:49

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:41', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4f38f475-a3aa-427e-898e-720c8f944c55'	System	21 Sep 2020 20:11:49
User entered 'No (N)'	System	21 Sep 2020 20:11:49

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:45', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4f38f475-a3aa-427e-898e-720c8f944c55'	System	21 Sep 2020 20:11:49
User entered 'None (1)'	System	21 Sep 2020 20:11:49

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:48', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4f38f475-a3aa-427e-898e-720c8f944c55'	System	21 Sep 2020 20:11:49
User entered '21 Sep 2020 13:11'	System	21 Sep 2020 20:11:49

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 6'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:29', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9b91bc85-d818-435c-8665-63e81b44637d'	System	23 Sep 2020 04:04:54
User entered 'None (1)'	System	23 Sep 2020 04:04:54

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:36', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9b91bc85-d818-435c-8665-63e81b44637d'	System	23 Sep 2020 04:04:54
User entered 'No (N)'	System	23 Sep 2020 04:04:54

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:40', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9b91bc85-d818-435c-8665-63e81b44637d'	System	23 Sep 2020 04:04:54
User entered 'No (N)'	System	23 Sep 2020 04:04:54

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:44', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9b91bc85-d818-435c-8665-63e81b44637d'	System	23 Sep 2020 04:04:54
User entered 'None (1)'	System	23 Sep 2020 04:04:54

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:52', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9b91bc85-d818-435c-8665-63e81b44637d'	System	23 Sep 2020 04:04:54
User entered '22 Sep 2020 21:04'	System	23 Sep 2020 04:04:54

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 7'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:12', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1c239ce1-d69d-406e-ba7b-404485b17e0f'	System	17 Sep 2020 18:44:42
User entered 'None (0)'	System	17 Sep 2020 18:44:42

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:18', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1c239ce1-d69d-406e-ba7b-404485b17e0f'	System	17 Sep 2020 18:44:42
User entered 'None (0)'	System	17 Sep 2020 18:44:42

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:21', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1c239ce1-d69d-406e-ba7b-404485b17e0f' User entered 'None (0)'	System	17 Sep 2020 18:44:42
	System	17 Sep 2020 18:44:42

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:25', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1c239ce1-d69d-406e-ba7b-404485b17e0f' User entered 'None (0)'	System	17 Sep 2020 18:44:42
	System	17 Sep 2020 18:44:42

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:28', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1c239ce1-d69d-406e-ba7b-404485b17e0f'	System	17 Sep 2020 18:44:42
User entered 'None (0)'	System	17 Sep 2020 18:44:42

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:32', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1c239ce1-d69d-406e-ba7b-404485b17e0f'	System	17 Sep 2020 18:44:42
User entered 'None (0)'	System	17 Sep 2020 18:44:42

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:36', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1c239ce1-d69d-406e-ba7b-404485b17e0f'	System	17 Sep 2020 18:44:42
User entered 'No (N)'	System	17 Sep 2020 18:44:42

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:40', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1c239ce1-d69d-406e-ba7b-404485b17e0f' User entered '17 Sep 2020 11:44'	System	17 Sep 2020 18:44:42
	System	17 Sep 2020 18:44:42

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:23'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 13:53'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:31', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '150f6549-18cd-4e0c-be33-1a892d1f9f53'	System	18 Sep 2020 17:12:05
User entered 'None (0)'	System	18 Sep 2020 17:12:05

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:35', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '150f6549-18cd-4e0c-be33-1a892d1f9f53'	System	18 Sep 2020 17:12:05
User entered 'None (0)'	System	18 Sep 2020 17:12:05

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:39', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '150f6549-18cd-4e0c-be33-1a892d1f9f53'	System	18 Sep 2020 17:12:05
User entered 'None (0)'	System	18 Sep 2020 17:12:05

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:43', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '150f6549-18cd-4e0c-be33-1a892d1f9f53'	System	18 Sep 2020 17:12:05
User entered 'None (0)'	System	18 Sep 2020 17:12:05

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:47', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '150f6549-18cd-4e0c-be33-1a892d1f9f53'	System	18 Sep 2020 17:12:05
User entered 'None (0)'	System	18 Sep 2020 17:12:05

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:50', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '150f6549-18cd-4e0c-be33-1a892d1f9f53'	System	18 Sep 2020 17:12:05
User entered 'None (0)'	System	18 Sep 2020 17:12:05

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:55', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '150f6549-18cd-4e0c-be33-1a892d1f9f53'	System	18 Sep 2020 17:12:05
User entered 'No (N)'	System	18 Sep 2020 17:12:05

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:12:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '150f6549-18cd-4e0c-be33-1a892d1f9f53'	System	18 Sep 2020 17:12:05
User entered '18 Sep 2020 10:12'	System	18 Sep 2020 17:12:05

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 14:48'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 2'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:14', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a2be35c6-4407-486f-a67e-3a5ff8940859'	System	19 Sep 2020 17:23:51
User entered 'None (0)'	System	19 Sep 2020 17:23:51

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:18', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a2be35c6-4407-486f-a67e-3a5ff8940859'	System	19 Sep 2020 17:23:51
User entered 'None (0)'	System	19 Sep 2020 17:23:51

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:22', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a2be35c6-4407-486f-a67e-3a5ff8940859'	System	19 Sep 2020 17:23:51
User entered 'None (0)'	System	19 Sep 2020 17:23:51

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:31', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a2be35c6-4407-486f-a67e-3a5ff8940859'	System	19 Sep 2020 17:23:51
User entered 'None (0)'	System	19 Sep 2020 17:23:51

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:35', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a2be35c6-4407-486f-a67e-3a5ff8940859'	System	19 Sep 2020 17:23:51
User entered 'None (0)'	System	19 Sep 2020 17:23:51

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:38', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a2be35c6-4407-486f-a67e-3a5ff8940859'	System	19 Sep 2020 17:23:51
User entered 'None (0)'	System	19 Sep 2020 17:23:51

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:45', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a2be35c6-4407-486f-a67e-3a5ff8940859'	System	19 Sep 2020 17:23:51
User entered 'No (N)'	System	19 Sep 2020 17:23:51

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:50', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a2be35c6-4407-486f-a67e-3a5ff8940859' User entered '19 Sep 2020 10:23'	System	19 Sep 2020 17:23:51
	System	19 Sep 2020 17:23:51

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 3'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:29', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9a7b12a1-ad06-4979-bf20-59f7523080d1'	System	20 Sep 2020 03:09:59
User entered 'None (0)'	System	20 Sep 2020 03:09:59

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:33', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9a7b12a1-ad06-4979-bf20-59f7523080d1' User entered 'None (0)'	System	20 Sep 2020 03:09:59
	System	20 Sep 2020 03:09:59

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:36', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9a7b12a1-ad06-4979-bf20-59f7523080d1'	System	20 Sep 2020 03:09:59
User entered 'None (0)'	System	20 Sep 2020 03:09:59

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:40', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9a7b12a1-ad06-4979-bf20-59f7523080d1'	System	20 Sep 2020 03:09:59
User entered 'None (0)'	System	20 Sep 2020 03:09:59

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:43', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9a7b12a1-ad06-4979-bf20-59f7523080d1' User entered 'None (0)'	System	20 Sep 2020 03:09:59
	System	20 Sep 2020 03:09:59

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:46', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9a7b12a1-ad06-4979-bf20-59f7523080d1' User entered 'None (0)'	System	20 Sep 2020 03:09:59
	System	20 Sep 2020 03:09:59

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:51', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9a7b12a1-ad06-4979-bf20-59f7523080d1'	System	20 Sep 2020 03:09:59
User entered 'No (N)'	System	20 Sep 2020 03:09:59

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:57', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9a7b12a1-ad06-4979-bf20-59f7523080d1'	System	20 Sep 2020 03:09:59
User entered '19 Sep 2020 20:09'	System	20 Sep 2020 03:09:59

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 4'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:21', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1bf35975-742e-4567-8895-3eb87eac37aa'	System	21 Sep 2020 04:57:49
User entered 'None (0)'	System	21 Sep 2020 04:57:49

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:25', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1bf35975-742e-4567-8895-3eb87eac37aa'	System	21 Sep 2020 04:57:49
User entered 'None (0)'	System	21 Sep 2020 04:57:49

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:28', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1bf35975-742e-4567-8895-3eb87eac37aa'	System	21 Sep 2020 04:57:49
User entered 'None (0)'	System	21 Sep 2020 04:57:49

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:32', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1bf35975-742e-4567-8895-3eb87eac37aa'	System	21 Sep 2020 04:57:49
User entered 'None (0)'	System	21 Sep 2020 04:57:49

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:35', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1bf35975-742e-4567-8895-3eb87eac37aa'	System	21 Sep 2020 04:57:49
User entered 'None (0)'	System	21 Sep 2020 04:57:49

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:38', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1bf35975-742e-4567-8895-3eb87eac37aa'	System	21 Sep 2020 04:57:49
User entered 'None (0)'	System	21 Sep 2020 04:57:49

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:42', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1bf35975-742e-4567-8895-3eb87eac37aa'	System	21 Sep 2020 04:57:49
User entered 'No (N)'	System	21 Sep 2020 04:57:49

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:46', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1bf35975-742e-4567-8895-3eb87eac37aa'	System	21 Sep 2020 04:57:49
User entered '20 Sep 2020 21:57'	System	21 Sep 2020 04:57:49

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 5'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:54', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '96fb0d94-4edb-4b22-93fc-0908bfcd7f99'	System	21 Sep 2020 20:12:18
User entered 'None (0)'	System	21 Sep 2020 20:12:18

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:57', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '96fb0d94-4edb-4b22-93fc-0908bfcd7f99'	System	21 Sep 2020 20:12:18
User entered 'None (0)'	System	21 Sep 2020 20:12:18

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:12:01', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '96fb0d94-4edb-4b22-93fc-0908bfcd7f99'	System	21 Sep 2020 20:12:18
User entered 'None (0)'	System	21 Sep 2020 20:12:18

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:12:04', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '96fb0d94-4edb-4b22-93fc-0908bfcd7f99'	System	21 Sep 2020 20:12:18
User entered 'None (0)'	System	21 Sep 2020 20:12:18

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:12:07', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '96fb0d94-4edb-4b22-93fc-0908bfcd7f99'	System	21 Sep 2020 20:12:18
User entered 'None (0)'	System	21 Sep 2020 20:12:18

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:12:09', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '96fb0d94-4edb-4b22-93fc-0908bfcd7f99'	System	21 Sep 2020 20:12:18
User entered 'None (0)'	System	21 Sep 2020 20:12:18

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:12:12', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '96fb0d94-4edb-4b22-93fc-0908bfcd7f99'	System	21 Sep 2020 20:12:18
User entered 'No (N)'	System	21 Sep 2020 20:12:18

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:12:16', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '96fb0d94-4edb-4b22-93fc-0908bfcd7f99'	System	21 Sep 2020 20:12:18
User entered '21 Sep 2020 13:12'	System	21 Sep 2020 20:12:18

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 6'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:58', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3b875891-f033-4e8b-9cd8-ee166b9a5d3b' User entered 'None (0)'	System	23 Sep 2020 04:05:30
	System	23 Sep 2020 04:05:30

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:05:02', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3b875891-f033-4e8b-9cd8-ee166b9a5d3b' User entered 'None (0)'	System	23 Sep 2020 04:05:30
	System	23 Sep 2020 04:05:30

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:05:08', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3b875891-f033-4e8b-9cd8-ee166b9a5d3b'	System	23 Sep 2020 04:05:30
User entered 'None (0)'	System	23 Sep 2020 04:05:30

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:05:12', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3b875891-f033-4e8b-9cd8-ee166b9a5d3b' User entered 'None (0)'	System	23 Sep 2020 04:05:30
	System	23 Sep 2020 04:05:30

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:05:16', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3b875891-f033-4e8b-9cd8-ee166b9a5d3b'	System	23 Sep 2020 04:05:30
User entered 'None (0)'	System	23 Sep 2020 04:05:30

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:05:19', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3b875891-f033-4e8b-9cd8-ee166b9a5d3b'	System	23 Sep 2020 04:05:30
User entered 'None (0)'	System	23 Sep 2020 04:05:30

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:05:23', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3b875891-f033-4e8b-9cd8-ee166b9a5d3b'	System	23 Sep 2020 04:05:30
User entered 'No (N)'	System	23 Sep 2020 04:05:30

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:05:27', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3b875891-f033-4e8b-9cd8-ee166b9a5d3b'	System	23 Sep 2020 04:05:30
User entered '22 Sep 2020 21:05'	System	23 Sep 2020 04:05:30

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 7'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

US3732110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

US3732110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:15:44
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	24 Sep 2020 20:17:56

US3732110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:15:44
User entered '24 Sep 2020'	Sylvia Lindholm (b) (4)	24 Sep 2020 20:17:56

US3732110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:15:44
User entered 'Contact Made (CONTACT MADE)'	Sylvia Lindholm (b) (4)	24 Sep 2020 20:17:56

US3732110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:15:44
User entered empty.	Sylvia Lindholm (b) (4)	24 Sep 2020 20:17:56

US3732110

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:16:39
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	24 Sep 2020 20:18:02

US3732110

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 20:18:02

US3732110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:18:40
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	01 Oct 2020 18:02:40

US3732110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:18:40
User entered '01 Oct 2020'	Linda Vega (b) (4)	01 Oct 2020 18:02:40
	(b) (4)	

US3732110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:18:40
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	01 Oct 2020 18:02:40

US3732110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:18:40
User entered empty.	Linda Vega (b) (4)	01 Oct 2020 18:02:40
	(b) (4)	

US3732110

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:18:48
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	01 Oct 2020 18:02:45

US3732110

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 18:02:45

US3732110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:23:39
User entered 'Yes (Y)'	Linda Vega (b) (4)	07 Oct 2020 21:29:48
	(b) (4)	

US3732110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:23:39
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 09:17:39
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'correct as is, visit occurred 21 days after visit 2' (Site from System).	Lauren Arnett (b) (4)	08 Oct 2020 16:40:06
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	07 Oct 2020 21:29:48
User entered '07 Oct 2020'	Linda Vega (b) (4)	07 Oct 2020 21:29:48

US3732110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:23:39
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	07 Oct 2020 21:29:48

US3732110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:23:39
User entered empty.	Linda Vega (b) (4) (b) (4)	07 Oct 2020 21:29:48

US3732110

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:38:28
User entered 'Yes (Y)'	Linda Vega (b) (4)	07 Oct 2020 21:29:52
	(b) (4)	

US3732110

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 21:29:52

US3732110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:48:08

US3732110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:48:08

US3732110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:48:08

US3732110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	20 Oct 2020 15:48:08

US3732110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

US3732110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

US3732110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '11:45'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

US3732110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:45'	System	20 Oct 2020 15:49:10

US3732110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

US3732110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

US3732110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

US3732110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '63'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

US3732110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Oct 2020 15:49:10

US3732110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '15'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

US3732110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Oct 2020 15:49:10

US3732110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '116'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

US3732110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Oct 2020 15:49:10

US3732110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '67'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

US3732110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Oct 2020 15:49:10

US3732110

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:48:26

US3732110

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:48:26

US3732110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:27

US3732110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:27

US3732110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '12:20'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:27

US3732110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:20'	System	20 Oct 2020 15:49:27

US3732110

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:31

US3732110

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 15:49:31

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 64'	System	20 Aug 2020 20:04:27

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-10-22T12:01:25', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '87530735-dc58-4a8b-9fe5-1f7f5b4ea9c4'	System	22 Oct 2020 19:02:31
User entered 'Yes (Y)'	System	22 Oct 2020 19:02:31

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Have you been exposed to someone with 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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-10-22T12:01:31', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '87530735-dc58-4a8b-9fe5-1f7f5b4ea9c4'	System	22 Oct 2020 19:02:31
User entered 'No (N)'	System	22 Oct 2020 19:02:31

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-10-22T12:01:40', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '87530735-dc58-4a8b-9fe5-1f7f5b4ea9c4'	System	22 Oct 2020 19:02:31
User entered 'No (N)'	System	22 Oct 2020 19:02:31

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-10-22T12:01:48', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '87530735-dc58-4a8b-9fe5-1f7f5b4ea9c4'	System	22 Oct 2020 19:02:31
User entered 'Yes (Y)'	System	22 Oct 2020 19:02:31

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Please 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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-10-22T12:02:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '87530735-dc58-4a8b-9fe5-1f7f5b4ea9c4'	System	22 Oct 2020 19:02:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Oct 2020 19:02:31

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-10-22T12:02:18', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '87530735-dc58-4a8b-9fe5-1f7f5b4ea9c4'	System	22 Oct 2020 19:02:31
User entered '22 Oct 2020 12:02:18'	System	22 Oct 2020 19:02:31

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 20:04:27

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 71'	System	20 Aug 2020 20:04:27

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-10-29T13:49:44', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'ca9c0ae4-bb01-43e0-936b-73831d4d6575'	System	29 Oct 2020 20:50:09
User entered 'No (N)'	System	29 Oct 2020 20:50:09

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Have you been exposed to someone with 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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-10-29T13:49:50', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'ca9c0ae4-bb01-43e0-936b-73831d4d6575'	System	29 Oct 2020 20:50:09
User entered 'No (N)'	System	29 Oct 2020 20:50:09

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-10-29T13:49:55', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'ca9c0ae4-bb01-43e0-936b-73831d4d6575'	System	29 Oct 2020 20:50:09
User entered '29 Oct 2020 13:49:55'	System	29 Oct 2020 20:50:09

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 20:04:27

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 78'	System	20 Aug 2020 20:04:27

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-11-03T08:10:34', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '38295953-36ad-4be9-bfe1-b075f57950a0'	System	03 Nov 2020 16:10:52
User entered 'No (N)'	System	03 Nov 2020 16:10:52

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Have you been exposed to someone with 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 (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-11-03T08:10:43', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '38295953-36ad-4be9-bfe1-b075f57950a0'	System	03 Nov 2020 16:10:52
User entered 'No (N)'	System	03 Nov 2020 16:10:52

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-11-03T08:10:49', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '38295953-36ad-4be9-bfe1-b075f57950a0' User entered '03 Nov 2020 08:10:49'	System	03 Nov 2020 16:10:52
	System	03 Nov 2020 16:10:52

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 20:04:27

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:04:27
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 20:04:27

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '17 Oct 2020 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '21 Oct 2020 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '24 Oct 2020 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '28 Oct 2020 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '31 Oct 2020 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '04 Nov 2020 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '07 Nov 2020 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '11 Nov 2020 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '14 Nov 2020 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '18 Nov 2020 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 00:06:36

US3732110

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	12 Nov 2020 19:18:05

US3732110

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Linda Vega (b) (4) (b) (4)	12 Nov 2020 19:18:05

US3732110

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	12 Nov 2020 19:18:05

US3732110

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Linda Vega (b) (4) (b) (4)	12 Nov 2020 19:18:05

US3732110

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	12 Nov 2020 19:18:10

US3732110

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 19:18:10

US3732110

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:12:49

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 23:23:33

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:17:01
User entered 'USA-US102-2020-mRNA-1273-P301000003'	System	19 Oct 2020 12:16:56
User entered 'New'	(b) (4), (b) (6)	19 Oct 2020 12:16:56

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Product issues, HLGT: Device issues, HLT: Device issues NEC, PT: Lead dislodgement, LLT: Displaced lead cardiac pacemaker - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Oct 2020 20:18:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Oct 2020 20:18:24
Data point term sent to Coder	System	16 Oct 2020 23:31:36
User entered 'Displaced Automated Implantable Cardioverter Defibrillator Lead'	(b) (4), (b) (6) (b) (4)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '08 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Oct 2020 00:25:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Oct 2020 00:25:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Oct 2020 00:25:13
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 23:30:49
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '08 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	17 Oct 2020 00:25:31
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	16 Oct 2020 23:30:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	17 Oct 2020 00:25:31
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		17 Oct 2020 00:25:31
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Oct 2020 00:25:31
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	16 Oct 2020 23:30:49
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

Action taken with investigational product

Audit	User	Time (GMT)
Query 'PV Query: Since the subject will not receive any more doses of study drug as both doses have already been provided, the correct action for study drug would be not applicable.' answered with 'updated' (Site from Safety).	Lauren Arnett (b) (4) (b) (4)	24 Nov 2020 20:08:55
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Lauren Arnett (b) (4) (b) (4)	24 Nov 2020 20:08:45
User opened query 'PV Query: Since the subject will not receive any more doses of study drug as both doses have already been provided, the correct action for study drug would be not applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 20:38:34
User closed query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 20:12:43
Query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'correct per eCRF guidelines. Not applicable only applies if prior to first dose' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 03:21:29
User opened query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 14:12:51
User entered 'None (NONE)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded therapeutic procedure that match this AE. Please review and update Other Action Taken as appropriate. Otherwise,clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 16:42:57
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded therapeutic procedure that match this AE. Please review and update Other Action Taken as appropriate. Otherwise,clarify.'	(b) (4), (b) (6)	10 Nov 2020 01:01:21
answered with 'Updated.' (Site from DM).		
User entered '0' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 01:00:59
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded therapeutic procedure that match this AE. Please review and update Other Action Taken as appropriate. Otherwise,clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:26:07
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 01:00:59
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none available, please state so.' answered with 'medical records have been requested ' (Site from Safety).	Lauren Arnett (b) (4)	24 Nov 2020 20:09:55
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none available, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 20:38:04
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none available, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 20:12:59
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none available, please state so.' answered with 'waiting on medical records' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 03:21:50
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none available, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 14:11:57
User entered 'During day 57 subject reported Implantable Device Replacement and during this procedure it was noted subject had a Displaced AICD Lead which resulted in one overnight stay for observation'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Oct 2020 23:30:49

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Post procedural pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 04:06:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 04:06:52
Data point term sent to Coder	System	16 Nov 2020 20:48:48
User entered 'post surgical pain bilateral shoulders related to displace automated implantable cardioverter defibrillator lead procedure'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '08 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[None](#)

Audit	User	Time (GMT)
User entered '1'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Nov 2020 20:48:27

US3732110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:12:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 20:48:27

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:12:49

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 17:41:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 17:41:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Arnett (b) (4)	21 Aug 2020 17:41:17
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 17:41:13
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 17:41:13

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:45:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:45:22
Data point term sent to Coder	System	21 Aug 2020 17:44:00
User entered 'levothyroxine'	Lauren Arnett (b) (4)	21 Aug 2020 17:43:40

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypothyroidism'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:43:40

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:43:40

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:43:40

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 06:56:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 06:56:39
Data point term sent to Coder Coding entries removed.	System Amara Yilmaz (b) (4) (b) (4)	30 Sep 2020 23:26:56 30 Sep 2020 23:26:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:47:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:47:26
Data point term sent to Coder User entered 'allopurinol'	System Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:05 21 Aug 2020 17:45:48

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 15:14:25
Query 'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'data updated to reflect location' (Site from DM).	Amara Yilmaz (b) (4) (b) (4)	30 Sep 2020 23:26:20
User entered 'GOUT Right big Toe' reason for change: New Information	Amara Yilmaz (b) (4) (b) (4)	30 Sep 2020 23:26:07
User opened query 'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:47:02
User entered 'gout'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'un UNK 1990'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:45:48

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:45:48

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:45:48

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 07:47:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 07:47:10
Data point term sent to Coder	System	21 Aug 2020 17:47:06
User entered 'metropol succinate ER'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'un UNK 1995'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:46:26

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:46:26

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:46:26

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: THIOCTIC ACID, PRODUCTSYNONYM: ALPHA LIPOIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 03:38:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 03:38:09
Data point term sent to Coder	System	16 Nov 2020 20:51:55
Coding entries removed.	Amara Yilmaz (b) (4)	16 Nov 2020 20:51:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: THIOCTIC ACID, PRODUCTSYNONYM: ALPHA LIPOIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:48:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:48:18
Data point term sent to Coder	System	21 Aug 2020 17:47:06
User entered 'alpha lipoic acid'	Lauren Arnett (b) (4)	21 Aug 2020 17:47:03

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:51:34
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

[Indication](#)

Audit	User	Time (GMT)
User entered 'vitamin deficiency' reason for change:	Amara Yilmaz (b) (4)	16 Nov 2020 20:51:34
New Information	(b) (4)	
User entered 'supplement'	Lauren Arnett (b) (4)	21 Aug 2020 17:47:03
	(b) (4)	

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '300'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'un UNK 1990'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 17:47:03

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:47:03

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:47:03

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS IC, PRODUCT: FLECAINIDE ACETATE, PRODUCTSYNONYM: TAMBOCOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 12:20:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 12:20:35
Data point term sent to Coder Coding entries removed.	System Amara Yilmaz (b) (4) (b) (4)	30 Sep 2020 23:27:57 30 Sep 2020 23:27:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS IC, PRODUCT: FLECAINIDE ACETATE, PRODUCTSYNONYM: TAMBOCOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 12:19:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 12:19:35
Data point term sent to Coder User entered 'flecainide acetate (tambocor)'	System Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:09 21 Aug 2020 17:48:18

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. type of ARRHYTHMIA) to the appropriate Medical History eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 15:14:34
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. type of ARRHYTHMIA) to the appropriate Medical History eCRF. ' answered with 'type of arrhythmia updated ' (Site from DM).	Amara Yilmaz (b) (4) (b) (4)	30 Sep 2020 23:28:36
User entered 'ARRHYTHMIA ventricular tachycardia' reason for change; Per Query Resolution	Amara Yilmaz (b) (4) (b) (4)	30 Sep 2020 23:27:07
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. type of ARRHYTHMIA) to the appropriate Medical History eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:48:26
User entered 'arrhythmia'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 17:48:18

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:48:18

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:48:18

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 07:00:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 07:00:38
Data point term sent to Coder	System	30 Sep 2020 23:29:58
Coding entries removed.	Amara Yilmaz (b) (4) (b) (4)	30 Sep 2020 23:29:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 04:47:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 04:47:33
Data point term sent to Coder	System	21 Aug 2020 17:49:10
User entered 'tamulosin (Flomax)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 15:14:38
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication. ' answered with 'data updated to reflect medical history condition ' (Site from DM).	Amara Yilmaz (b) (4) (b) (4)	30 Sep 2020 23:30:02
User entered 'benign prostatic hyperplasia' reason for change: Data Entry Error	Amara Yilmaz (b) (4) (b) (4)	30 Sep 2020 23:29:36
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:49:33
User entered 'enlarged prostate'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 18:38:28
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'data has been corrected ' (Site from DM).	Amara Yilmaz (b) (4) (b) (4)	20 Nov 2020 21:47:15
User entered '0.4' reason for change: Data Entry Error	Amara Yilmaz (b) (4) (b) (4)	20 Nov 2020 21:46:56
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 09:21:43
User entered '4'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:48:57

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:48:57

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:48:57

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:51:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:51:24
Data point term sent to Coder	System	21 Aug 2020 17:50:11
User entered 'aspirin'	Lauren Arnett (b) (4)	21 Aug 2020 17:49:30

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

[Indication](#)

Audit	User	Time (GMT)
User entered 'cardiac health'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'un UNK 1980'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:49:30

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:49:30

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:49:30

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

[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: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:51:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:51:24
Data point term sent to Coder	System	21 Aug 2020 17:50:11
User entered 'simvastatin'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

[Indication](#)

Audit	User	Time (GMT)
User entered 'hyperlipidemia'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'un UNK 1980'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:50:02

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:50:02

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:50:02

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 08:08:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 08:08:29
Data point term sent to Coder	System	20 Oct 2020 15:55:44
User entered 'keflex'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

[Indication](#)

Audit	User	Time (GMT)
Query 'Per ETRTR: If medication was dosed for SAE "DISPLACED AUTOMATED IMPLANTABLE CARDIOVERTER DEFIBRILLATOR LEAD", please state so within SAE CRF, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 21:25:37
User opened query 'Per ETRTR: If medication was dosed for SAE "DISPLACED AUTOMATED IMPLANTABLE CARDIOVERTER DEFIBRILLATOR LEAD", please state so within SAE CRF, thanks.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 21:23:50
User entered 'pacemaker replacement procedure'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '250'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '08 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Oct 2020 15:54:59

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 15:54:59

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 15:54:59

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 15:58:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 15:58:38
Data point term sent to Coder	System	20 Oct 2020 15:57:47
User entered 'tylenol'	Amara Yilmaz (b) (4)	20 Oct 2020 15:57:10
	(b) (4)	

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

[Indication](#)

Audit	User	Time (GMT)
User entered 'pacemaker replacement procedure'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '08 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 15:57:10

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 15:57:10

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 15:57:10

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 02:12:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 02:12:50
Data point term sent to Coder	System	16 Nov 2020 20:50:52
User entered 'colchicine'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

[Indication](#)

Audit	User	Time (GMT)
User entered 'gout right big toe'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.6'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '01 Nov 2020'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 20:50:41

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 20:50:41

US3732110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Nov 2020 20:50:41

US3732110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:12:49

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:50:18

US3732110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:12:49

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:50:41

US3732110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:12:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'PACEMAKER REPLACEMENT'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:50:41

US3732110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:12:49

[Indication](#)

Audit	User	Time (GMT)
User entered 'Medical History (MH)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:50:41

US3732110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:12:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:50:41

US3732110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:12:49

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:51:58

US3732110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:12:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'automated implantable cardioverter defibrillator lead replacement'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:51:58

US3732110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:12:49

[Indication](#)

Audit	User	Time (GMT)
User entered 'Medical History (MH)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:51:58

US3732110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:12:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:51:58

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'USA-US102-2020-MRNA-1273-P301000003'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Yes (Y)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Yes (Y)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Scott'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Overcash'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered '5565 Grossmont Center Dr'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'La Mesa'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'CA'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered '91942'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:54:52
User entered 'US'	System	19 Oct 2020 12:19:44

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Nov 2020 19:55:15
User entered '1'	System	19 Oct 2020 12:19:44

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'USA-US102-2020-MRNA-1273-P301000003'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Yes (Y)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Yes (Y)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Scott'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Overcash'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered '5565 Grossmont Center Dr'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'La Mesa'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'CA'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered '91942'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:54:52
User entered 'US'	System	19 Oct 2020 12:19:44

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Nov 2020 19:55:15
User entered '1'	System	19 Oct 2020 12:19:44

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:12:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '19/Oct/2020 12:19'	System	19 Oct 2020 12:19:44

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:12:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:54:52
User entered '1'	(b) (4), (b) (6)	19 Oct 2020 12:19:44

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'USA-US102-2020-MRNA-1273-P301000003'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Yes (Y)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Yes (Y)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Scott'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Overcash'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered '5565 Grossmont Center Dr'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'La Mesa'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'CA'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered '91942'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:54:52
User entered 'US'	System	19 Oct 2020 12:19:44

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Nov 2020 19:55:15
User entered '1'	System	19 Oct 2020 12:19:44

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:12:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '10/Nov/2020 14:55'	System	10 Nov 2020 19:55:15

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:12:49

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)	10 Nov 2020 19:55:15

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'USA-US102-2020-MRNA-1273-P301000003'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Yes (Y)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Yes (Y)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Scott'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Overcash'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered '5565 Grossmont Center Dr'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'La Mesa'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'CA'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered '91942'	System	19 Oct 2020 12:16:56

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:54:52
User entered 'US'	System	19 Oct 2020 12:19:44

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Nov 2020 19:55:15
User entered '1'	System	19 Oct 2020 12:19:44

US3732110

Folder: SAE USA-US102-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:12:49

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 '0'	(b) (4), (b) (6)	10 Nov 2020 19:55:15