

US3432023 (Prod: Brigham and Womens Hospital)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:25:41

All time stamps listed in this document are displayed in GMT

US3432023

Form: Participant Creation

Generated On: 26 Nov 2020 09:25:41

[Participant ID](#)

US3432023

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

US3432023

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3432023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:41

Date of Birth (MMM yyyy)	(b) (6) 1937
Age	83
Age Units	YEARS
Age (Derived)	83
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

US3432023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:41

Date of Informed Consent (<i>dd MMM yyyy</i>)	5 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

US3432023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:25:41

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3432023

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:25:41

Were any significant conditions reported?

Yes ☒

No ☐

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:41

Condition	AORTIC STENOSIS
Start date (dd MMM yyyy)	UN JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:41

Condition	CONGESTIVE HEART FAILURE
Start date (dd MMM yyyy)	UN JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:41

Condition	MILD DEPRESSION
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)	_____

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:41

Condition	MONOCLONAL GAMMOPATHY OF UNDETERMINED SIGNIFICANCE
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:41

Condition	MILD RENAL FAILURE
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:41

Condition	CHRONIC ANEMIA
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:41

Condition	STROKE
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:41

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

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:41

Condition	PENICILLIN ALLERGY (SERUM SICKNESS)
Start date (dd MMM yyyy)	UN UNK 1960
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 1960
Start Year (derived)	1960
Stop Month and Year (derived)	
Stop Year (derived)	

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:41

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:41

Condition	CHRONIC LOW BACK PAIN WITH INTERMITTENT FLARE
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)	

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:41

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

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:41

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)	

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:41

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

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:41

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

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:41

Condition	CORONARY HEART DISEASE
Start date (dd MMM yyyy)	UN NOV 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:25:41

Condition	TAVR FOR AORTIC STENOSIS
Start date (dd MMM yyyy)	UN JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN JUN 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUN 2019
Stop Year (derived)	2019

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:25:41

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

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	5 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:24 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 12:24
Height (<i>xxx.x</i>)	171.1 cm
Weight (<i>xxx.x</i>)	77.0 kg
BMI (<i>xxx.x</i>)	26.30212 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)	

US3432023

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 AUG 2020

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

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☒	No ☐
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐	No ☒
Retail or Restaurant Operations , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐	No ☒
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐	No ☒
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐	No ☒
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐	No ☒
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐	No ☒
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐	No ☒
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐	No ☒
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐	No ☒
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐	No ☒
Other	Yes ☐	No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

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

US3432023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3432023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:41

What was the date of randomization? (dd MMM yyyy) 05 AUG 2020

What was the participant's randomization number? 184652

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 ☒

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:41

Height	ND - Not Done
Weight	ND - Not Done

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

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)	5 AUG 2020
Time of assessment (00:00-23:59)	12:24 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 12:24
Temperature (xxx.x)	36.9 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	060 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	015 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	072 mmHg
Diastolic Blood Pressure units	MMHG

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

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)	5 AUG 2020
Time of assessment (00:00-23:59)	14:24 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 14:24
Temperature (xxx.x)	36.9 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	061 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	015 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	065 mmHg
Diastolic Blood Pressure units	MMHG

US3432023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

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.

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

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)	5 AUG 2020
What was the treatment time? (00:00-23:59)	13:54 (24 HR)
Treatment Date and Time (derived)	5 AUG 2020 13:54
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

US3432023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	5 AUG 2020
Collection time (<i>00:00-23:59</i>)	13:00 (24 HR)
Collection date and time (derived)	5 AUG 2020 13:00

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:25:41

Collection date (dd MMM yyyy)			5 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:05	5 AUG 2020 13:05
Nasopharyngeal Swab 2	No		

US3432023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

05 AUG 2020 14:33

PC Open Date & Time

05 AUG 2020 14:14

PC Close Date & Time

05 AUG 2020 16:44

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °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	06 AUG 2020 09:11
PC Open Date & Time	05 AUG 2020 17:39
PC Close Date & Time	06 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	98.6 °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):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	07 AUG 2020 04:04
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:41

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

97.9 °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

08 AUG 2020 08:57

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	98.4 °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):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	09 AUG 2020 06:43
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

10 AUG 2020 09:42

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 07:07

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

12 AUG 2020 09:48

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

DAY 8

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 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

DAY 9

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 13 AUG 2020 12:00

PC Close Date & Time 14 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

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

05 AUG 2020 14:34

PC Open Date & Time

05 AUG 2020 14:14

PC Close Date & Time

05 AUG 2020 16:44

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

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

06 AUG 2020 09:12

PC Open Date & Time

05 AUG 2020 17:39

PC Close Date & Time

06 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:41

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

07 AUG 2020 04:05

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:41

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

08 AUG 2020 08:57

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:41

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

09 AUG 2020 06:43

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:41

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

10 AUG 2020 09:42

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:41

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

11 AUG 2020 07:08

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:41

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

12 AUG 2020 09:48

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 14:34
PC Open Date & Time	05 AUG 2020 14:14
PC Close Date & Time	05 AUG 2020 16:44

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 09:13
PC Open Date & Time	05 AUG 2020 17:39
PC Close Date & Time	06 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:41

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 ☒

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:41

Yes ☐	
PC Time stamp	07 AUG 2020 04:06
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:41

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 ☒

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:41

Yes ☐	
PC Time stamp	08 AUG 2020 08:58
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:41

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 ☒

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:41

Yes ☐	
PC Time stamp	09 AUG 2020 06:44
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:41

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 ☒

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:41

Yes ☐	
PC Time stamp	10 AUG 2020 09:42
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:41

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 ☒

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:41

Yes ☐	
PC Time stamp	11 AUG 2020 07:09
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:41

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 ☒

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:41

Yes ☐	
PC Time stamp	12 AUG 2020 09:49
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3432023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

Was Contact Attempted?

Yes ☒

No ☐

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

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	02 SEP 2020
Time of assessment (00:00-23:59)	14:06 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 14:06
Temperature (xxx.x)	36.4 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	174 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

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

US3432023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

Was study treatment given? Yes ☐
No ☒

If No, reason not given

Participant declined due to ☐
Adverse Event ☐
Physician withheld dose due to ☒
Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by ☐
Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3432023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	02 SEP 2020
Collection time (<i>00:00-23:59</i>)	13:35 (24 HR)
Collection date and time (derived)	02 SEP 2020 13:35

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:25:41

Collection date (dd MMM yyyy)			02 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:07	02 SEP 2020 14:07
Nasopharyngeal Swab 2	No		

US3432023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

Was Contact Attempted?

Yes ☒

No ☐

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

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	01 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	01 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	15:17 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 15:17
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	61 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

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.

US3432023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	01 OCT 2020
Collection time (<i>00:00-23:59</i>)	15:44 (24 HR)
Collection date and time (derived)	01 OCT 2020 15:44

US3432023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 NOV 2020 15:13:42
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 13:49:18

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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 2020 00:01

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03 NOV 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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06 NOV 2020 00:01

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10 NOV 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2020 00:01

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17 NOV 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 10:22:34
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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08 DEC 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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22 DEC 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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29 DEC 2020 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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08 JAN 2021 00:01

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12 JAN 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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15 JAN 2021 00:01

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19 JAN 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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19 FEB 2021 00:01

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23 FEB 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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26 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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°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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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°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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

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08 FEB 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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11 FEB 2022 00:01

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15 FEB 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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18 FEB 2022 00:01

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22 FEB 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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°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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

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01 MAR 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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08 MAR 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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25 MAR 2022 00:01

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US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

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05 APR 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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08 APR 2022 00:01

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12 APR 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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15 APR 2022 00:01

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19 APR 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

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26 APR 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

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31 MAY 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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°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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

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07 JUN 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

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14 JUN 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

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21 JUN 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

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28 JUN 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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05 JUL 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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08 JUL 2022 00:01

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12 JUL 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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15 JUL 2022 00:01

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19 JUL 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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22 JUL 2022 00:01

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26 JUL 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

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02 AUG 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

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05 AUG 2022 00:01

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09 AUG 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3432023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

Was Contact Attempted?

Yes ☒

No ☐

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

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432023

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:25:41

Date of Contact	7 AUG 2020
Time of Contact	11:00
Date and Time of Contact (derived)	7 AUG 2020 11:00
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 ☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	7 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	37.0 C	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	317 of 2162	

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	8 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	321 of 2162	

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	9 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	325 of 2162	

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	10 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	329 of 2162	

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	333 of 2162	

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	12 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	337 of 2162	

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	6 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	341 of 2162	

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:25:41

Date of Visit	7 AUG 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐ No ☒
Date of Test	7 AUG 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	0

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:25:41

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:25:41

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	09 AUG 2020
Day 5	No	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3432023

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	7 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	7 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:47 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 11:47
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	37 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	58 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432023

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 AUG 2020

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

US3432023

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:25:41

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

7 AUG 2020

US3432023

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3432023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

US3432023

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

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.

US3432023

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:25:41

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection _____

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:25:41

Visit Date	07 AUG 2020
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	True
Immunogenicity Assessment	True
Pregnancy Test	False

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	7 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:47 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 11:47
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	058 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	063 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 AUG 2020

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

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	7 AUG 2020
Collection time (<i>00:00-23:59</i>)	12:07 (24 HR)
Collection date and time (derived)	7 AUG 2020 12:07

US3432023

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:25:41

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

AEID	USA-US078-2020-MRNA-1273-P30 1000001
Adverse event	POSSIBLE POLYMYALGIA RHEUMATICA
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)	20 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	20 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	21 AUG 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

360 of 2162

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☒ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

24AUG20, WE RECEIVED RHEUMATOLOGY ATTENDING CONSULTATION NOTE WHO SAW PT 21AUG20 AT HOSPITAL. SPOKE W/ RHEUMATOLOGIST TO DISCUSS CASE IN DETAIL. AT TIME OF ENROLLMENT PT FELT WELL. HOWEVER, PT NOTED HE MAY HAVE STARTED TO HAVE BACK PAIN A FEW DAYS BEFORE RECEIVING IP. SYMPTOMS AT THAT TIME WERE MILD & THOUGHT TO BE RELATED TO HIS CHRONIC BACK PAIN. HE RECEIVED IP ON 5AUG20 & REPORTED INCREASED BACK PAIN OVER THE NEXT DAYS & PROGRESSIVELY DEVELOPED MIGRATORY MYALGIAS (BACK, SHOULDERS, OCCIPUT, PARASPINAL MUSCLES) & WEAKNESS. DENIED ANY LOCAL INJECTION SITE REACTION AFTER VACCINATION. THE MYALGIAS BECAME SEVERE 20AUG20, & HE WAS NOT ABLE TO GET OF OUT BED BECAUSE OF GENERALIZED WEAKNESS. HE WAS HOSPITALIZED BETWEEN 20AUG20 AND 21AUG20. WORK-UP 20AUG20 NOTABLE FOR CRP AT 96.9 MG/L (REF 0.0-5.0) AND ESR AT 56 MM/H (REF 0-15). HE RECEIVED 15 MG

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

OF PREDNISONE ON 20AUG20.
FELT MUCH BETTER 21AUG20 &
DISCHARGED W/
PRESCRIPTION OF PREDNISONE
20 MG DAILY, WITH A
PLANNED TAPERING OVER 16
DAYS.

AT THIS TIME
RHEUMATOLOGIST THINKS
PMR MAY BE POSSIBLE
DIAGNOSIS. BACK PAIN
PRESENT BEFORE THE IP
ADMINISTRATION, BUT
POLYMYALGIA AND
WEAKNESS DEVELOPED AFTER
VACCINE ADMINISTRATION.
WE ARE UPDATING AE TO
INCLUDE ADDITIONAL
SYMPTOMS. GIVEN THIS
ADDITIONAL INFORMATION,
THE CONSULTATION WITH THE
TREATING RHEUMATOLOGIST,
& TIMING OF DEVELOPMENT
OF THESE SYMPTOMS IT IS
POSSIBLE THAT VACCINE MAY
HAVE CONTRIBUTED TO THE
SYMPTOMS. THUS, WE ARE
CHANGING OUR ASSESSMENT
THAT THERE MAY BE A
POSSIBLE RELATIONSHIP
BETWEEN THE
SYMPTOMATOLOGY OF PT
AND THE STUDY PRODUCT.
AS OF TODAY HE FEELS GOOD
DURING THE DAY, BUT WAKES
UP IN MORNING WITH SOME
PAIN IN THE SHOULDERS

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

AND NECK. THE PAIN GOES
AWAY APPROXIMATELY 2
HOURS AFTER TAKING THE 20
MG DOSE OF PREDNISONE. HE
REMAINS IN CLOSE CONTACT
WITH HIS
RHEUMATOLOGIST.COVID
TEST 20AUG20- NEGATIVE
PT FELT BETTER W/
PREDNISONE. OFF PREDNISONE
AROUND 4SEP20 W/
RECURRENCE OF AXIAL
MYALGIAS. WENT TO RHEUM
9SEP20. ON 20MG PREDNISONE
FOR 2 WEEKS THEN SLOW
TAPER

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

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:25:41

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

Yes ☒

No ☐

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

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ☒
Indication	STROKE
Dose per administration	325
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 ☐

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

	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 2011
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	☒

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

Name of Medication	PLAVIX
Prophylaxis	Yes ☐ No ☒
Indication	STROKE
Dose per administration	75
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

	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 2011
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	☒

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

Name of Medication	BUPROPION
Prophylaxis	Yes ☐ No ☒
Indication	DEPRESSION
Dose per administration	150
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

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)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

Name of Medication	MULTIVITIMIN
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

	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	☒

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

Name of Medication	VITAMIN D
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
Dose per administration	2000
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☒ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

	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	☒

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

Name of Medication	CALCIUM
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
Dose per administration	1000
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 ☐

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

	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	☒

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

Name of Medication	BISOPROLOL
Prophylaxis	Yes ☐ No ☒
Indication	HEART FAILURE/HTN
Dose per administration	2.5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	UN	JUL 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

Name of Medication	LEVOTHYRONINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPOTHYROIDISM
Dose per administration	1.2
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

	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 2005
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	☒

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC LOW BACK PAIN WITH INTERMITTENT FLARE
Dose per administration	325
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 ☐

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

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

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

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

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

	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)		21 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 04 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

Name of Medication	PREDNISONE
Prophylaxis	Yes ☐ No ☒
Indication	POSSIBLE POLYMYALGIA RHEUMATICA
Dose per administration	15
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

	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)		20 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		20 AUG 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

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

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

	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)		11 SEP 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	☒

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

Name of Medication	ROSUVASTATIN
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 ☐

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

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

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

Name of Medication	ATENOLOL
Prophylaxis	Yes ☐ No ☒
Indication	PREMATURE VENTRICULAR COMPLEX
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 ☐

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

Name of Medication	COLASE
Prophylaxis	Yes ☐ No ☒
Indication	CONSTIPATION
Dose per administration	UNK
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNK
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 ☐

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

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

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

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

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

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

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

Name of Medication	FLU VACCINE
Prophylaxis	Yes ☒
	No ☐
Indication	PROPHYLAXIS FOR INFLUENZA
Dose per administration	1
Dose unit	mg ☐
	ug ☐
	mL ☐
	g ☐
	IU ☐
	tablet ☐
	capsule ☐
	puff ☐
	Other ☒
If dose unit is Other, specify	INJECTION
Frequency	once daily ☐
	twice daily ☐
	three times daily ☐
	four times daily ☐
	every other day ☐
	every week ☐
	every month ☐
	as needed ☐
	once ☒
	unknown ☐
	other ☐
If frequency is Other, specify	
Route of administration	Oral ☐
	Topical ☐
	Subcutaneous ☐
	Transdermal ☐
	Intraocular ☐
	Intramuscular ☒

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

	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)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		25 SEP 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	☐

US3432023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:25:41

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3432023

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:25:41

Date of dosing discontinuation (dd MMM yyyy)

26 AUG 2020

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

SAE #1

US3432023

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:25:41

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 ☐

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

SAEID	USA-US078-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:25:41

SAEID	USA-US078-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	21/AUG/2020 09:37
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

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:25:41

SAEID	USA-US078-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	24/AUG/2020 11:19
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

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:25:41

SAEID	USA-US078-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	26/AUG/2020 10:11
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

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:25:41

SAEID	USA-US078-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	27/AUG/2020 09:43
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

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:25:41

SAEID	USA-US078-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	17/SEP/2020 08:34
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

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:25:41

SAEID	USA-US078-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	15/OCT/2020 09:43
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

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 09:25:41

SAEID	USA-US078-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	22/OCT/2020 20:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3432023 (Prod: Brigham and Womens Hospital)

US3432023

Form: Participant Creation

Generated On: 26 Nov 2020 09:25:41

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3432023'	RWS_ENDPOINT ENDPOINT (b) (4) 	05 Aug 2020 16:14:23

US3432023

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Aug 2020 16:19:40

US3432023

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	05 Aug 2020 16:14:24

US3432023

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Aug 2020 16:19:40

US3432023

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	05 Aug 2020 16:19:40

US3432023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered (b) (6) 1937'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	05 Aug 2020 16:14:25

US3432023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:41

[Age](#)

Audit	User	Time (GMT)
User entered '83'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:41

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:41

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '83'	System	05 Aug 2020 16:21:40

US3432023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:41

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:41

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:41

White

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:41

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:41

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:41

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:41

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:41

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:41

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:41

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:41

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 16:21:02

US3432023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '5 Aug 2020'	(b) (4), (b) (6)	05 Aug 2020 16:21:40

US3432023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	05 Aug 2020 16:21:40

US3432023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2020'	System	05 Aug 2020 16:21:40

US3432023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:41

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	05 Aug 2020 16:21:40

US3432023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Aug 2020 16:21:40

US3432023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 16:21:40

US3432023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:41

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 16:21:40

US3432023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:41

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 16:21:40

US3432023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:41

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	05 Aug 2020 16:14:24

US3432023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:41

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 16:46:14

US3432023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Aug 2020 16:46:14

US3432023

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:25:41

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:58:25

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Aortic stenosis, LLT: Aortic stenosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 22:34:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 22:34:38
Data point term sent to Coder	System	21 Oct 2020 22:33:52
Coding entries removed.	Jun Bai Park Chang (b) (4)	21 Oct 2020 22:33:10
User entered 'AORTIC STENOSIS' reason for change: Per Query Resolution	Jun Bai Park Chang (b) (4)	21 Oct 2020 22:33:10
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Aortic stenosis, LLT: Aortic stenosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 07:19:03
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 07:19:03
Data point term sent to Coder	System	05 Aug 2020 22:59:21
User entered 'Aortic stenosis s/p TAVR'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Un Jun 2019'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Either review and confirm to add a stop date as surgical procedures are not expected to remain ongoing, or, split events/conditions/procedures and record them as separate MHs. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:15:16
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Either review and confirm to add a stop date as surgical procedures are not expected to remain ongoing, or, split events/conditions/procedures and record them as separate MHs. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Jun Bai Park Chang (b) (4)	21 Oct 2020 22:33:15
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Either review and confirm to add a stop date as surgical procedures are not expected to remain ongoing, or, split events/conditions/procedures and record them as separate MHs. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:37:32
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jun 2019'	System	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2019'	System	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 22:59:03

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:01:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:01:06
Data point term sent to Coder	System	05 Aug 2020 23:00:21
User entered 'congestive heart failure'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'UN Jun 2019'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jun 2019'	System	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2019'	System	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 22:59:39

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 23:01:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 23:01:06
Data point term sent to Coder	System	05 Aug 2020 23:00:22
User entered 'mild depression'	Monica Feeley (b) (4)	05 Aug 2020 22:59:57
	(b) (4)	

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'UN UNK 1980'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '1980'	System	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 22:59:57

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:41

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per MM: Please confirm this MH condition does not meet exclusion criteria #11 (Immunosuppressive or immunodeficient state, asplenia, recurrent severe infections)' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:04:07
Query 'Per MM: Please confirm this MH condition does not meet exclusion criteria #11 (Immunosuppressive or immunodeficient state, asplenia, recurrent severe infections)' answered with 'this is not considered an immunosuppressive state. No IS treatment. Pt does not have multiple myeloma ' (Site from DM).	Monica Feeley (b) (4)	14 Oct 2020 21:00:30
User opened query 'Per MM: Please confirm this MH condition does not meet exclusion criteria #11 (Immunosuppressive or immunodeficient state, asplenia, recurrent severe infections)' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:37:28
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Plasma cell neoplasms, HLT: Plasma cell neoplasms NEC, PT: Hypergammaglobulinaemia benign monoclonal, LLT: Monoclonal gammopathy of unknown significance - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 09:46:27
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 09:46:27
Data point term sent to Coder	System	05 Aug 2020 23:00:24
User entered 'monoclonal gammopathy of undetermined significance'	Monica Feeley (b) (4)	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2012'	System	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 23:00:23

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Renal failure, LLT: Renal failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:48:13
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:48:13
Data point term sent to Coder	System	05 Aug 2020 23:01:24
User entered 'Mild renal failure'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Un UNK 2013'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2013'	System	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 23:00:43

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:41

Condition

Audit	User	Time (GMT)
User closed query 'Per MM: Please update to reflect the etiology, if known. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 10:41:09
Query 'Per MM: Please update to reflect the etiology, if known. ' answered with 'etiology unknown' (Site from DM).	Monica Feeley (b) (4)	30 Sep 2020 17:45:02
User opened query 'Per MM: Please update to reflect the etiology, if known. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:37:46
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Chronic anemia - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 23:02:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 23:02:02
Data point term sent to Coder	System	05 Aug 2020 23:01:25
User entered 'Chronic Anemia'	Monica Feeley (b) (4)	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2012'	System	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 23:01:01

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:02:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:02:02
Data point term sent to Coder	System	05 Aug 2020 23:01:25
User entered 'Stroke'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Un UNK 2011'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'UN UNK 2011'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jan 2011'	System	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2011'	System	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jan 2011'	System	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2011'	System	05 Aug 2020 23:01:15

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Streptococcal infections, PT: Pneumonia pneumococcal, LLT: Pneumococcal pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:04:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:04:02
Data point term sent to Coder	System	05 Aug 2020 23:03:27
User entered 'Pneumococcal Pneumonia'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2010'	System	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2010'	System	05 Aug 2020 23:02:39

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:41

[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: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 12:35:44
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 12:35:44
Data point term sent to Coder	System	31 Aug 2020 20:12:24
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:12:11
User entered 'PENICILLIN ALLERGY (serum sickness)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:12:11
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: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:04:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:04:02
Data point term sent to Coder	System	05 Aug 2020 23:03:27
User entered 'Penicillin Allergy'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Un UNK 1960'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jan 1960'	System	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '1960'	System	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 23:02:54

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:41

[Condition](#)

Audit	User	Time (GMT)
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)	05 Aug 2020 23:04:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 23:04:02
Data point term sent to Coder	System	05 Aug 2020 23:03:27
User entered 'Hypothyroidism'	Monica Feeley (b) (4)	05 Aug 2020 23:03:06
	(b) (4)	

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2005'	System	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 23:03:06

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 15:43:37
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 15:43:37
Data point term sent to Coder	System	11 Aug 2020 17:32:19
User entered 'Chronic low back pain with intermittent flare'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'UN UNK 2000'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2000'	System	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:31:28

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:41

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 10:41:33
Query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'no reported treatment' (Site from DM).	Monica Feeley (b) (4)	30 Sep 2020 17:48:54
User opened query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:38:34
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 11:08:49
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 11:08:49
Data point term sent to Coder	System	31 Aug 2020 20:13:27
Coding entries removed.	Monica Feeley (b) (4)	31 Aug 2020 20:12:37
User entered 'HYPERTENSION (well controlled)' reason for change: Data Entry Error	Monica Feeley (b) (4)	31 Aug 2020 20:12:37
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 21:43:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 21:43:31
Data point term sent to Coder	System	25 Aug 2020 21:42:21
User entered 'Hypertension'	Monica Feeley (b) (4)	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Un UNK 2010'	Monica Feeley (b) (4) (b) (4)	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2010'	System	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 21:41:29

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:41

[Condition](#)

Audit	User	Time (GMT)
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)	12 Sep 2020 19:39:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 19:39:35
Data point term sent to Coder	System	12 Sep 2020 19:38:59
User entered 'Hyperlipidemia'	Monica Feeley (b) (4)	12 Sep 2020 19:38:28
	(b) (4)	

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'UN UNK 1980'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '1980'	System	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:38:28

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Ventricular extrasystoles, LLT: Premature ventricular contractions - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Sep 2020 04:56:40
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Sep 2020 04:56:40
Data point term sent to Coder	System	12 Sep 2020 19:39:00
User entered 'Premature Ventricular Complex'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2010'	System	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:38:45

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 19:40:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 19:40:35
Data point term sent to Coder	System	12 Sep 2020 19:40:00
User entered 'Constipation'	Monica Feeley (b) (4)	12 Sep 2020 19:39:04
	(b) (4)	

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'UN Jan 2020'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2020'	System	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:39:04

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary heart disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 19:40:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 19:40:35
Data point term sent to Coder	System	12 Sep 2020 19:40:00
User entered 'Coronary Heart Disease'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'UN Nov 2019'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Nov 2019'	System	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:39:24

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:25:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac valve therapeutic procedures, PT: Transcatheter aortic valve implantation, LLT: Transcatheter aortic valve implantation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 06:46:39
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 06:46:39
Data point term sent to Coder	System	10 Nov 2020 21:25:48
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 21:25:37
User entered 'TAVR for Aortic Stenosis' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 21:25:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac valve therapeutic procedures, PT: Transcatheter aortic valve implantation, LLT: Transcatheter aortic valve implantation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 12:06:34
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 12:06:34
Data point term sent to Coder	System	21 Oct 2020 22:34:52
User entered 's/p TAVR'	Jun Bai Park Chang (b) (4)	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'un Jun 2019'	Jun Bai Park Chang (b) (4)	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jun Bai Park Chang (b) (4)	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:25:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'un Jun 2019'	Jun Bai Park Chang (b) (4)	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:25:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jun Bai Park Chang (b) (4)	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jun 2019'	System	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2019'	System	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jun 2019'	System	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2019'	System	21 Oct 2020 22:33:54

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:25:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 21:27:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 21:27:40
Data point term sent to Coder	System	10 Nov 2020 21:26:49
User entered 'Seasonal allergies'	Monica Feeley (b) (4)	10 Nov 2020 21:26:40
	(b) (4)	

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Un UNK 2010'	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:25:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:25:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '2010'	System	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:26:40

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '5 Aug 2020'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '12:24'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '5 Aug 2020 12:24'	System	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '171.1' cm	Monica Feeley (b) (4)	05 Aug 2020 22:57:59
DataPoint set to visible.	(b) (4) System	05 Aug 2020 16:46:14

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '77.0' kg	Monica Feeley (b) (4)	05 Aug 2020 22:57:59
DataPoint set to visible.	(b) (4) System	05 Aug 2020 16:46:14

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '26.30212'	System	16 Sep 2020 23:44:01
User entered '26.3'	System	05 Aug 2020 22:57:59
DataPoint set to visible.	System	05 Aug 2020 16:46:14

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	05 Aug 2020 22:57:59
DataPoint set to visible.	System	05 Aug 2020 16:46:14

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Jessica Cauley (b) (4)	13 Aug 2020 18:00:20
User entered '36.9' C	Monica Feeley (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:19:43
Query 'Data is required. Please provide.' answered with 'no its not' (Site from System).	Jessica Cauley (b) (4)	13 Aug 2020 18:00:26
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 18:00:20
User entered empty; reason for change Per Query Resolution	Jessica Cauley (b) (4)	13 Aug 2020 18:00:20
User entered 'Oral (Oral)'	Monica Feeley (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Jessica Cauley (b) (4)	13 Aug 2020 18:00:20
User entered '060'	Monica Feeley (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Jessica Cauley (b) (4)	13 Aug 2020 18:00:20
User entered '015'	Monica Feeley (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Jessica Cauley (b) (4)	13 Aug 2020 18:00:20
User entered '160'	Monica Feeley (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Jessica Cauley (b) (4)	13 Aug 2020 18:00:20
User entered '072'	Monica Feeley (b) (4)	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 22:57:59

US3432023

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:52:26

US3432023

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	08 Sep 2020 03:36:56
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		02 Sep 2020 22:24:14
User entered '5 Aug 2020'	Monica Feeley (b) (4)	05 Aug 2020 22:52:26
	(b) (4)	

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '1'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:41

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:19:24

US3432023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Aug 2020 16:57:11

US3432023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '05 Aug 2020' reason for change: Per Query Resolution	Xhoi Mitre (b) (4)	10 Nov 2020 15:35:18
User entered '5 Aug 2020'	(b) (4), (b) (6)	05 Aug 2020 16:57:11

US3432023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Aug 2020 16:57:11

US3432023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	05 Aug 2020 16:57:11

US3432023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	05 Aug 2020 16:49:32

US3432023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:41

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:15:14
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:15:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 16:49:32
User entered '184652' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	05 Aug 2020 16:49:32

US3432023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	05 Aug 2020 16:49:32

US3432023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 16:58:18

US3432023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Aug 2020 16:58:18

US3432023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 16:58:18

US3432023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 16:58:18

US3432023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:41

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 16:58:18

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:41

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:41

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:41

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:41

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Aug 2020'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '12:24'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '5 Aug 2020 12:24'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.9' C	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '060'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '015'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 13:06:59
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Blood pressure is NCS and pre dose baseline blood pressure so AE not applicable.' (Site from System).	Monica Feeley (b) (4)	06 Aug 2020 12:00:29
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	05 Aug 2020 23:16:10
User entered '160'	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '072'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:41

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:41

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '5 Aug 2020'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:39:07
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol fine' (Site from System).	Monica Feeley (b) (4)	05 Aug 2020 23:39:06
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		05 Aug 2020 23:16:10
User entered '14:24'	Monica Feeley (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '5 Aug 2020 14:24'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.9' C	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '061'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '015'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '143'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '065'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 23:16:10

US3432023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:52:16

US3432023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 22:52:16

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '5 Aug 2020'	(b) (4), (b) (6)	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '13:54'	(b) (4), (b) (6)	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '5 Aug 2020 13:54'	System	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	05 Aug 2020 18:03:29

US3432023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:17:43

US3432023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '5 Aug 2020'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:17:43

US3432023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '13:00'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:17:43

US3432023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '5 Aug 2020 13:00'	System	05 Aug 2020 23:17:43

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '5 Aug 2020'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:18:02

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:41

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:18:02

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:18:02

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '13:05'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:18:02

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '5 Aug 2020 13:05'	System	05 Aug 2020 23:18:02

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:41

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Monica Feeley (b) (4)	05 Aug 2020 23:18:02

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:18:02

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:18:02

US3432023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 23:18:02

US3432023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:17:24

US3432023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 23:17:24

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:32:53', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '3d405960-897d-4dd1-9b7b-299b23de07b3'	System	05 Aug 2020 18:33:39
User entered 'Yes (Y)'	System	05 Aug 2020 18:33:39

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:33:19', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '3d405960-897d-4dd1-9b7b-299b23de07b3'	System	05 Aug 2020 18:33:39
User entered '98.4'	System	05 Aug 2020 18:33:39

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:33:26', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '3d405960-897d-4dd1-9b7b-299b23de07b3'	System	05 Aug 2020 18:33:39
User entered 'No (N)'	System	05 Aug 2020 18:33:39

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:33:36', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '3d405960-897d-4dd1-9b7b-299b23de07b3'	System	05 Aug 2020 18:33:39
User entered '05 Aug 2020 14:33'	System	05 Aug 2020 18:33:39

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 14:14'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 16:44'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:10:05', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '9bf8e60c-6f49-4b0a-a35c-3cc5c6f25119'	System	06 Aug 2020 13:11:11
User entered 'Yes (Y)'	System	06 Aug 2020 13:11:11

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:10:23', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '9bf8e60c-6f49-4b0a-a35c-3cc5c6f25119'	System	06 Aug 2020 13:11:11
User entered '98.4'	System	06 Aug 2020 13:11:11

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:10:39', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '9bf8e60c-6f49-4b0a-a35c-3cc5c6f25119'	System	06 Aug 2020 13:11:11
User entered 'No (N)'	System	06 Aug 2020 13:11:11

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:11:08', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '9bf8e60c-6f49-4b0a-a35c-3cc5c6f25119'	System	06 Aug 2020 13:11:11
User entered '06 Aug 2020 09:11'	System	06 Aug 2020 13:11:11

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 17:39'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 2'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:03:16', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '025e8fde-7065-476c-b549-88dd1c5108eb'	System	07 Aug 2020 08:04:34
User entered 'Yes (Y)'	System	07 Aug 2020 08:04:34

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:03:44', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '025e8fde-7065-476c-b549-88dd1c5108eb' User entered '98.6'	System	07 Aug 2020 08:04:34

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:03:47', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '025e8fde-7065-476c-b549-88dd1c5108eb' User entered 'Yes (Y)'	System	07 Aug 2020 08:04:34

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 09:51:54
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:04:21', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '025e8fde-7065-476c-b549-88dd1c5108eb' User entered '1'	Monica Feeley (b) (4)	31 Aug 2020 19:43:52
	System	07 Aug 2020 08:04:34
	System	07 Aug 2020 08:04:34
	System	07 Aug 2020 08:04:34

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:04:21', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '025e8fde-7065-476c-b549-88dd1c5108eb' User entered '0'	System	07 Aug 2020 08:04:34

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:04:28', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '025e8fde-7065-476c-b549-88dd1c5108eb' User entered '07 Aug 2020 04:04'	System	07 Aug 2020 08:04:34
	System	07 Aug 2020 08:04:34

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 3'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:56:23', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2ab0b369-a3cc-4a1d-94b2-7820fd8f3b42'	System	08 Aug 2020 12:57:03
User entered 'Yes (Y)'	System	08 Aug 2020 12:57:03

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:56:45', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2ab0b369-a3cc-4a1d-94b2-7820fd8f3b42'	System	08 Aug 2020 12:57:03
User entered '97.9'	System	08 Aug 2020 12:57:03

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:56:52', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2ab0b369-a3cc-4a1d-94b2-7820fd8f3b42'	System	08 Aug 2020 12:57:03
User entered 'No (N)'	System	08 Aug 2020 12:57:03

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:01', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2ab0b369-a3cc-4a1d-94b2-7820fd8f3b42'	System	08 Aug 2020 12:57:03
User entered '08 Aug 2020 08:57'	System	08 Aug 2020 12:57:03

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 4'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:42:36', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'ae3a4179-4f47-4bb7-b800-31393f263214'	System	09 Aug 2020 10:43:15
User entered 'Yes (Y)'	System	09 Aug 2020 10:43:15

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:41

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:43:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'ae3a4179-4f47-4bb7-b800-31393f263214'	System	09 Aug 2020 10:43:15
User entered '98.4'	System	09 Aug 2020 10:43:15

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:41:30', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'ae3a4179-4f47-4bb7-b800-31393f263214'	System	09 Aug 2020 10:43:15
User entered 'Yes (Y)'	System	09 Aug 2020 10:43:15

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 09:52:04
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:40:23', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'ae3a4179-4f47-4bb7-b800-31393f263214' User entered '1'	Monica Feeley (b) (4)	31 Aug 2020 19:44:07
	System	09 Aug 2020 10:43:15
	System	09 Aug 2020 10:43:15
	System	09 Aug 2020 10:43:15

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:40:23', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'ae3a4179-4f47-4bb7-b800-31393f263214' User entered '0'	System	09 Aug 2020 10:43:15

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:43:13', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'ae3a4179-4f47-4bb7-b800-31393f263214'	System	09 Aug 2020 10:43:15
User entered '09 Aug 2020 06:43'	System	09 Aug 2020 10:43:15

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 5'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:41:47', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'fc8d317a-91d4-4b79-ba07-fd7971069bc1'	System	10 Aug 2020 13:42:10
User entered 'Yes (Y)'	System	10 Aug 2020 13:42:10

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:41:58', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'fc8d317a-91d4-4b79-ba07-fd7971069bc1'	System	10 Aug 2020 13:42:10
User entered '98.4'	System	10 Aug 2020 13:42:10

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:03', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'fc8d317a-91d4-4b79-ba07-fd7971069bc1'	System	10 Aug 2020 13:42:10
User entered 'No (N)'	System	10 Aug 2020 13:42:10

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:09', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'fc8d317a-91d4-4b79-ba07-fd7971069bc1'	System	10 Aug 2020 13:42:10
User entered '10 Aug 2020 09:42'	System	10 Aug 2020 13:42:10

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 6'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:07:29', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '280a23e5-042b-4919-947b-a7ebae742fad'	System	11 Aug 2020 11:07:55
User entered 'Yes (Y)'	System	11 Aug 2020 11:07:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:07:40', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '280a23e5-042b-4919-947b-a7ebae742fad'	System	11 Aug 2020 11:07:55
User entered '97.6'	System	11 Aug 2020 11:07:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:07:46', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '280a23e5-042b-4919-947b-a7ebae742fad'	System	11 Aug 2020 11:07:55
User entered 'No (N)'	System	11 Aug 2020 11:07:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:07:51', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '280a23e5-042b-4919-947b-a7ebae742fad'	System	11 Aug 2020 11:07:55
User entered '11 Aug 2020 07:07'	System	11 Aug 2020 11:07:55

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 7'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:47:20', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b3070df5-7116-40ee-8e75-e5c761573a4c'	System	12 Aug 2020 13:48:13
User entered 'Yes (Y)'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:47:37', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b3070df5-7116-40ee-8e75-e5c761573a4c'	System	12 Aug 2020 13:48:13
User entered '97.4'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:47:48', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b3070df5-7116-40ee-8e75-e5c761573a4c'	System	12 Aug 2020 13:48:13
User entered 'Yes (Y)'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 09:52:15
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b3070df5-7116-40ee-8e75-e5c761573a4c' User entered '1'	Monica Feeley (b) (4)	31 Aug 2020 19:44:32
	System	12 Aug 2020 13:48:13
	System	12 Aug 2020 13:48:13
	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b3070df5-7116-40ee-8e75-e5c761573a4c'	System	12 Aug 2020 13:48:13
User entered '0'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:11', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b3070df5-7116-40ee-8e75-e5c761573a4c'	System	12 Aug 2020 13:48:13
User entered '12 Aug 2020 09:48'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 13:48:13
User entered 'Day 8'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 13:48:13
User entered 'Day 9'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:33:46', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '27572070-434d-47cc-a8a8-08f8226c91f1'	System	05 Aug 2020 18:34:19
User entered 'None (1)'	System	05 Aug 2020 18:34:19

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:33:57', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '27572070-434d-47cc-a8a8-08f8226c91f1'	System	05 Aug 2020 18:34:19
User entered 'No (N)'	System	05 Aug 2020 18:34:19

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:01', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '27572070-434d-47cc-a8a8-08f8226c91f1'	System	05 Aug 2020 18:34:19
User entered 'No (N)'	System	05 Aug 2020 18:34:19

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:10', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '27572070-434d-47cc-a8a8-08f8226c91f1'	System	05 Aug 2020 18:34:19
User entered 'None (1)'	System	05 Aug 2020 18:34:19

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:17', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '27572070-434d-47cc-a8a8-08f8226c91f1'	System	05 Aug 2020 18:34:19
User entered '05 Aug 2020 14:34'	System	05 Aug 2020 18:34:19

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 14:14'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 16:44'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:11:20', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34fe363c-c058-4cd0-bc56-0700182384be' User entered 'None (1)'	System	06 Aug 2020 13:12:28
	System	06 Aug 2020 13:12:28

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:11:26', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34fe363c-c058-4cd0-bc56-0700182384be'	System	06 Aug 2020 13:12:28
User entered 'No (N)'	System	06 Aug 2020 13:12:28

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:12:16', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34fe363c-c058-4cd0-bc56-0700182384be'	System	06 Aug 2020 13:12:28
User entered 'No (N)'	System	06 Aug 2020 13:12:28

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:12:22', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34fe363c-c058-4cd0-bc56-0700182384be' User entered 'None (1)'	System	06 Aug 2020 13:12:28

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:12:27', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34fe363c-c058-4cd0-bc56-0700182384be'	System	06 Aug 2020 13:12:28
User entered '06 Aug 2020 09:12'	System	06 Aug 2020 13:12:28

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 17:39'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 2'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:41

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:04:40', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '65a501ea-f93d-45ed-9c4e-b634024552e0'	System	07 Aug 2020 08:05:08
User entered 'None (1)'	System	07 Aug 2020 08:05:08

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:04:43', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '65a501ea-f93d-45ed-9c4e-b634024552e0'	System	07 Aug 2020 08:05:08
User entered 'No (N)'	System	07 Aug 2020 08:05:08

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:04:47', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '65a501ea-f93d-45ed-9c4e-b634024552e0'	System	07 Aug 2020 08:05:08
User entered 'No (N)'	System	07 Aug 2020 08:05:08

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:04:55', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '65a501ea-f93d-45ed-9c4e-b634024552e0'	System	07 Aug 2020 08:05:08
User entered 'None (1)'	System	07 Aug 2020 08:05:08

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:05:03', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '65a501ea-f93d-45ed-9c4e-b634024552e0'	System	07 Aug 2020 08:05:08
User entered '07 Aug 2020 04:05'	System	07 Aug 2020 08:05:08

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 3'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:10', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '1ca15cb4-9978-4d3a-ac73-c49583758635'	System	08 Aug 2020 12:57:35
User entered 'None (1)'	System	08 Aug 2020 12:57:35

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:14', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '1ca15cb4-9978-4d3a-ac73-c49583758635'	System	08 Aug 2020 12:57:35
User entered 'No (N)'	System	08 Aug 2020 12:57:35

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:19', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '1ca15cb4-9978-4d3a-ac73-c49583758635'	System	08 Aug 2020 12:57:35
User entered 'No (N)'	System	08 Aug 2020 12:57:35

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:25', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '1ca15cb4-9978-4d3a-ac73-c49583758635'	System	08 Aug 2020 12:57:35
User entered 'None (1)'	System	08 Aug 2020 12:57:35

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:31', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '1ca15cb4-9978-4d3a-ac73-c49583758635'	System	08 Aug 2020 12:57:35
User entered '08 Aug 2020 08:57'	System	08 Aug 2020 12:57:35

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 4'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:41

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:43:20', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2e4f66e0-d46d-4468-87a8-c926dc9a5a1f'	System	09 Aug 2020 10:43:40
User entered 'None (1)'	System	09 Aug 2020 10:43:40

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:43:23', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2e4f66e0-d46d-4468-87a8-c926dc9a5a1f'	System	09 Aug 2020 10:43:40
User entered 'No (N)'	System	09 Aug 2020 10:43:40

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:43:27', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2e4f66e0-d46d-4468-87a8-c926dc9a5a1f'	System	09 Aug 2020 10:43:40
User entered 'No (N)'	System	09 Aug 2020 10:43:40

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:43:32', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2e4f66e0-d46d-4468-87a8-c926dc9a5a1f'	System	09 Aug 2020 10:43:40
User entered 'None (1)'	System	09 Aug 2020 10:43:40

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:43:36', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2e4f66e0-d46d-4468-87a8-c926dc9a5a1f'	System	09 Aug 2020 10:43:40
User entered '09 Aug 2020 06:43'	System	09 Aug 2020 10:43:40

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 5'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:14', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '4bbfb502-70e5-4b52-ae52-734a8870c429'	System	10 Aug 2020 13:42:32
User entered 'None (1)'	System	10 Aug 2020 13:42:32

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:19', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '4bbfb502-70e5-4b52-ae52-734a8870c429'	System	10 Aug 2020 13:42:32
User entered 'No (N)'	System	10 Aug 2020 13:42:32

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:22', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '4bbfb502-70e5-4b52-ae52-734a8870c429'	System	10 Aug 2020 13:42:32
User entered 'No (N)'	System	10 Aug 2020 13:42:32

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:26', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '4bbfb502-70e5-4b52-ae52-734a8870c429'	System	10 Aug 2020 13:42:32
User entered 'None (1)'	System	10 Aug 2020 13:42:32

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:29', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '4bbfb502-70e5-4b52-ae52-734a8870c429'	System	10 Aug 2020 13:42:32
User entered '10 Aug 2020 09:42'	System	10 Aug 2020 13:42:32

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 6'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:41

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:00', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8f7342cf-beb4-4f77-81c8-d392950b9f49'	System	11 Aug 2020 11:08:21
User entered 'None (1)'	System	11 Aug 2020 11:08:21

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:04', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8f7342cf-beb4-4f77-81c8-d392950b9f49'	System	11 Aug 2020 11:08:21
User entered 'No (N)'	System	11 Aug 2020 11:08:21

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:08', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8f7342cf-beb4-4f77-81c8-d392950b9f49'	System	11 Aug 2020 11:08:21
User entered 'No (N)'	System	11 Aug 2020 11:08:21

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:12', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8f7342cf-beb4-4f77-81c8-d392950b9f49'	System	11 Aug 2020 11:08:21
User entered 'None (1)'	System	11 Aug 2020 11:08:21

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:17', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8f7342cf-beb4-4f77-81c8-d392950b9f49'	System	11 Aug 2020 11:08:21
User entered '11 Aug 2020 07:08'	System	11 Aug 2020 11:08:21

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 7'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:22', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34bda301-f9ec-44e9-9b17-807659b3398f'	System	12 Aug 2020 13:48:46
User entered 'None (1)'	System	12 Aug 2020 13:48:46

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:28', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34bda301-f9ec-44e9-9b17-807659b3398f'	System	12 Aug 2020 13:48:46
User entered 'No (N)'	System	12 Aug 2020 13:48:46

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:33', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34bda301-f9ec-44e9-9b17-807659b3398f'	System	12 Aug 2020 13:48:46
User entered 'No (N)'	System	12 Aug 2020 13:48:46

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:38', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34bda301-f9ec-44e9-9b17-807659b3398f'	System	12 Aug 2020 13:48:46
User entered 'None (1)'	System	12 Aug 2020 13:48:46

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:43', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '34bda301-f9ec-44e9-9b17-807659b3398f'	System	12 Aug 2020 13:48:46
User entered '12 Aug 2020 09:48'	System	12 Aug 2020 13:48:46

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:25', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b177d4ed-dc54-4062-b68d-43a74d3aad6d'	System	05 Aug 2020 18:34:53
User entered 'None (0)'	System	05 Aug 2020 18:34:53

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:27', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b177d4ed-dc54-4062-b68d-43a74d3aad6d'	System	05 Aug 2020 18:34:53
User entered 'None (0)'	System	05 Aug 2020 18:34:53

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:31', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b177d4ed-dc54-4062-b68d-43a74d3aad6d'	System	05 Aug 2020 18:34:53
User entered 'None (0)'	System	05 Aug 2020 18:34:53

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:35', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b177d4ed-dc54-4062-b68d-43a74d3aad6d'	System	05 Aug 2020 18:34:53
User entered 'None (0)'	System	05 Aug 2020 18:34:53

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:39', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b177d4ed-dc54-4062-b68d-43a74d3aad6d'	System	05 Aug 2020 18:34:53
User entered 'None (0)'	System	05 Aug 2020 18:34:53

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:41', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b177d4ed-dc54-4062-b68d-43a74d3aad6d'	System	05 Aug 2020 18:34:53
User entered 'None (0)'	System	05 Aug 2020 18:34:53

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:45', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b177d4ed-dc54-4062-b68d-43a74d3aad6d'	System	05 Aug 2020 18:34:53
User entered 'No (N)'	System	05 Aug 2020 18:34:53

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-05T14:34:51', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'b177d4ed-dc54-4062-b68d-43a74d3aad6d'	System	05 Aug 2020 18:34:53
User entered '05 Aug 2020 14:34'	System	05 Aug 2020 18:34:53

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 14:14'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 16:44'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:13:01', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '708687be-9d93-4e88-9511-ed753196fec9'	System	06 Aug 2020 13:14:00
User entered 'None (0)'	System	06 Aug 2020 13:14:00

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:13:09', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '708687be-9d93-4e88-9511-ed753196fec9'	System	06 Aug 2020 13:14:00
User entered 'No interference with activity (1)'	System	06 Aug 2020 13:14:00

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:13:20', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '708687be-9d93-4e88-9511-ed753196fec9'	System	06 Aug 2020 13:14:00
User entered 'No interference with activity (1)'	System	06 Aug 2020 13:14:00

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:13:29', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '708687be-9d93-4e88-9511-ed753196fec9'	System	06 Aug 2020 13:14:00
User entered 'None (0)'	System	06 Aug 2020 13:14:00

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:13:33', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '708687be-9d93-4e88-9511-ed753196fec9'	System	06 Aug 2020 13:14:00
User entered 'None (0)'	System	06 Aug 2020 13:14:00

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:13:43', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '708687be-9d93-4e88-9511-ed753196fec9'	System	06 Aug 2020 13:14:00
User entered 'None (0)'	System	06 Aug 2020 13:14:00

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:13:52', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '708687be-9d93-4e88-9511-ed753196fec9'	System	06 Aug 2020 13:14:00
User entered 'No (N)'	System	06 Aug 2020 13:14:00

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-06T09:13:58', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '708687be-9d93-4e88-9511-ed753196fec9'	System	06 Aug 2020 13:14:00
User entered '06 Aug 2020 09:13'	System	06 Aug 2020 13:14:00

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 17:39'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:41

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 2'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:05:18', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'c62fe1f0-bae2-4829-8e25-73b4a99b0790'	System	07 Aug 2020 08:06:21
User entered 'None (0)'	System	07 Aug 2020 08:06:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:05:37', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'c62fe1f0-bae2-4829-8e25-73b4a99b0790'	System	07 Aug 2020 08:06:21
User entered 'No interference with activity (1)'	System	07 Aug 2020 08:06:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:05:48', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'c62fe1f0-bae2-4829-8e25-73b4a99b0790'	System	07 Aug 2020 08:06:21
User entered 'None (0)'	System	07 Aug 2020 08:06:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:05:53', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'c62fe1f0-bae2-4829-8e25-73b4a99b0790'	System	07 Aug 2020 08:06:21
User entered 'None (0)'	System	07 Aug 2020 08:06:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:05:56', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'c62fe1f0-bae2-4829-8e25-73b4a99b0790'	System	07 Aug 2020 08:06:21
User entered 'None (0)'	System	07 Aug 2020 08:06:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:06:06', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'c62fe1f0-bae2-4829-8e25-73b4a99b0790'	System	07 Aug 2020 08:06:21
User entered 'None (0)'	System	07 Aug 2020 08:06:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:06:14', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'c62fe1f0-bae2-4829-8e25-73b4a99b0790'	System	07 Aug 2020 08:06:21
User entered 'No (N)'	System	07 Aug 2020 08:06:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-07T04:06:19', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'c62fe1f0-bae2-4829-8e25-73b4a99b0790'	System	07 Aug 2020 08:06:21
User entered '07 Aug 2020 04:06'	System	07 Aug 2020 08:06:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 3'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:41', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '87b962c6-0264-4392-9d14-3580ffa0b5e9'	System	08 Aug 2020 12:58:21
User entered 'None (0)'	System	08 Aug 2020 12:58:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:44', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '87b962c6-0264-4392-9d14-3580ffa0b5e9'	System	08 Aug 2020 12:58:21
User entered 'None (0)'	System	08 Aug 2020 12:58:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:49', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '87b962c6-0264-4392-9d14-3580ffa0b5e9'	System	08 Aug 2020 12:58:21
User entered 'None (0)'	System	08 Aug 2020 12:58:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:53', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '87b962c6-0264-4392-9d14-3580ffa0b5e9'	System	08 Aug 2020 12:58:21
User entered 'None (0)'	System	08 Aug 2020 12:58:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:57:58', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '87b962c6-0264-4392-9d14-3580ffa0b5e9'	System	08 Aug 2020 12:58:21
User entered 'None (0)'	System	08 Aug 2020 12:58:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:58:01', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '87b962c6-0264-4392-9d14-3580ffa0b5e9'	System	08 Aug 2020 12:58:21
User entered 'None (0)'	System	08 Aug 2020 12:58:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:58:12', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '87b962c6-0264-4392-9d14-3580ffa0b5e9'	System	08 Aug 2020 12:58:21
User entered 'No (N)'	System	08 Aug 2020 12:58:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-08T08:58:19', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '87b962c6-0264-4392-9d14-3580ffa0b5e9'	System	08 Aug 2020 12:58:21
User entered '08 Aug 2020 08:58'	System	08 Aug 2020 12:58:21

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 4'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:43:54', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '75496574-a10a-49f8-814e-423a8e5572e8' User entered 'None (0)'	System	09 Aug 2020 10:44:37
	System	09 Aug 2020 10:44:37

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:44:03', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '75496574-a10a-49f8-814e-423a8e5572e8' User entered 'None (0)'	System	09 Aug 2020 10:44:37
	System	09 Aug 2020 10:44:37

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:44:07', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '75496574-a10a-49f8-814e-423a8e5572e8'	System	09 Aug 2020 10:44:37
User entered 'None (0)'	System	09 Aug 2020 10:44:37

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:44:12', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '75496574-a10a-49f8-814e-423a8e5572e8' User entered 'None (0)'	System	09 Aug 2020 10:44:37
	System	09 Aug 2020 10:44:37

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:44:16', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '75496574-a10a-49f8-814e-423a8e5572e8'	System	09 Aug 2020 10:44:37
User entered 'None (0)'	System	09 Aug 2020 10:44:37

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:44:20', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '75496574-a10a-49f8-814e-423a8e5572e8' User entered 'None (0)'	System	09 Aug 2020 10:44:37
	System	09 Aug 2020 10:44:37

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:44:25', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '75496574-a10a-49f8-814e-423a8e5572e8'	System	09 Aug 2020 10:44:37
User entered 'No (N)'	System	09 Aug 2020 10:44:37

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-09T06:44:35', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '75496574-a10a-49f8-814e-423a8e5572e8' User entered '09 Aug 2020 06:44'	System	09 Aug 2020 10:44:37
	System	09 Aug 2020 10:44:37

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 5'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:35', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '94827b0e-f830-4ed7-a004-c7989aa99c7e'	System	10 Aug 2020 13:43:01
User entered 'None (0)'	System	10 Aug 2020 13:43:01

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:39', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '94827b0e-f830-4ed7-a004-c7989aa99c7e'	System	10 Aug 2020 13:43:01
User entered 'None (0)'	System	10 Aug 2020 13:43:01

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:42', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '94827b0e-f830-4ed7-a004-c7989aa99c7e' User entered 'None (0)'	System	10 Aug 2020 13:43:01
	System	10 Aug 2020 13:43:01

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:46', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '94827b0e-f830-4ed7-a004-c7989aa99c7e' User entered 'None (0)'	System	10 Aug 2020 13:43:01
	System	10 Aug 2020 13:43:01

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:49', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '94827b0e-f830-4ed7-a004-c7989aa99c7e'	System	10 Aug 2020 13:43:01
User entered 'None (0)'	System	10 Aug 2020 13:43:01

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:52', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '94827b0e-f830-4ed7-a004-c7989aa99c7e'	System	10 Aug 2020 13:43:01
User entered 'None (0)'	System	10 Aug 2020 13:43:01

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:56', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '94827b0e-f830-4ed7-a004-c7989aa99c7e'	System	10 Aug 2020 13:43:01
User entered 'No (N)'	System	10 Aug 2020 13:43:01

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-10T09:42:59', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '94827b0e-f830-4ed7-a004-c7989aa99c7e' User entered '10 Aug 2020 09:42'	System	10 Aug 2020 13:43:01
	System	10 Aug 2020 13:43:01

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 6'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:37', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2990a9a3-eac6-4b78-82ff-a75f76525411'	System	11 Aug 2020 11:09:09
User entered 'No interference with activity (1)'	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:41', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2990a9a3-eac6-4b78-82ff-a75f76525411'	System	11 Aug 2020 11:09:09
User entered 'None (0)'	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:45', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2990a9a3-eac6-4b78-82ff-a75f76525411'	System	11 Aug 2020 11:09:09
User entered 'None (0)'	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:49', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2990a9a3-eac6-4b78-82ff-a75f76525411'	System	11 Aug 2020 11:09:09
User entered 'None (0)'	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:53', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2990a9a3-eac6-4b78-82ff-a75f76525411'	System	11 Aug 2020 11:09:09
User entered 'None (0)'	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:08:56', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2990a9a3-eac6-4b78-82ff-a75f76525411'	System	11 Aug 2020 11:09:09
User entered 'None (0)'	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:09:02', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2990a9a3-eac6-4b78-82ff-a75f76525411'	System	11 Aug 2020 11:09:09
User entered 'No (N)'	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-11T07:09:08', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '2990a9a3-eac6-4b78-82ff-a75f76525411'	System	11 Aug 2020 11:09:09
User entered '11 Aug 2020 07:09'	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 7'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:55', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8d3c131e-fc12-4362-b434-a445ad1dca0c'	System	12 Aug 2020 13:49:36
User entered 'None (0)'	System	12 Aug 2020 13:49:36

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:48:59', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8d3c131e-fc12-4362-b434-a445ad1dca0c' User entered 'None (0)'	System	12 Aug 2020 13:49:36
	System	12 Aug 2020 13:49:36

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:49:04', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8d3c131e-fc12-4362-b434-a445ad1dca0c'	System	12 Aug 2020 13:49:36
User entered 'None (0)'	System	12 Aug 2020 13:49:36

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:49:14', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8d3c131e-fc12-4362-b434-a445ad1dca0c' User entered 'None (0)'	System	12 Aug 2020 13:49:36
	System	12 Aug 2020 13:49:36

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:49:18', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8d3c131e-fc12-4362-b434-a445ad1dca0c'	System	12 Aug 2020 13:49:36
User entered 'None (0)'	System	12 Aug 2020 13:49:36

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:49:22', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8d3c131e-fc12-4362-b434-a445ad1dca0c' User entered 'None (0)'	System	12 Aug 2020 13:49:36
	System	12 Aug 2020 13:49:36

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:41

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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:49:29', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8d3c131e-fc12-4362-b434-a445ad1dca0c'	System	12 Aug 2020 13:49:36
User entered 'No (N)'	System	12 Aug 2020 13:49:36

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-08-12T09:49:33', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '8d3c131e-fc12-4362-b434-a445ad1dca0c'	System	12 Aug 2020 13:49:36
User entered '12 Aug 2020 09:49'	System	12 Aug 2020 13:49:36

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 11:09:09
User entered 'Day 8'	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 11:09:09

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 13:48:13
User entered 'Day 9'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 13:48:13

US3432023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 13:48:13

US3432023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	19 Aug 2020 16:12:57

US3432023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Phoebe Cunningham (b) (4)	19 Aug 2020 16:12:57

US3432023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	19 Aug 2020 16:12:57

US3432023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	19 Aug 2020 16:12:57

US3432023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	19 Aug 2020 16:13:02

US3432023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 16:13:02

US3432023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	19 Aug 2020 16:13:11

US3432023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Phoebe Cunningham (b) (4)	19 Aug 2020 16:13:11

US3432023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	19 Aug 2020 16:13:11

US3432023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	19 Aug 2020 16:13:11

US3432023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	19 Aug 2020 16:13:16

US3432023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 16:13:16

US3432023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	27 Aug 2020 00:16:46

US3432023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Phoebe Cunningham (b) (4)	27 Aug 2020 00:16:46

US3432023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	27 Aug 2020 00:16:46

US3432023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	27 Aug 2020 00:16:46

US3432023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	27 Aug 2020 00:16:59

US3432023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 00:16:59

US3432023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:24:14

US3432023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '02 Sep 2020'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:24:14

US3432023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:24:14

US3432023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	02 Sep 2020 22:24:14

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Sep 2020'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '14:06'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '02 Sep 2020 14:06'	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.4' C	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '55'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '16'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 12:43:32
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Hypertension noted in medical history as pre-existing condition' (Site from System).	Bruce Bausk (b) (4)	02 Sep 2020 22:33:38
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Sep 2020 22:30:50
User entered '174'	Bruce Bausk (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '72'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:30:50

US3432023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:32:34

US3432023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 Sep 2020'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:32:34

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

[If No, reason not given](#)

Audit	User	Time (GMT)
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		02 Sep 2020 22:32:10
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)' reason for change: Data Entry Error	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:32:10
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	02 Sep 2020 22:31:48
User entered empty.	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:31:48

US3432023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 23:30:56

US3432023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '02 Sep 2020'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 23:30:56

US3432023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '13:35'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 23:30:56

US3432023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '02 Sep 2020 13:35'	System	02 Sep 2020 23:30:56

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:25:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Sep 2020'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 23:31:09

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:41

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 23:31:09

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 23:31:09

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '14:07'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 23:31:09

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '02 Sep 2020 14:07'	System	02 Sep 2020 23:31:09

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:41

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 23:31:09

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 23:31:09

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	02 Sep 2020 23:31:09

US3432023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 23:31:09

US3432023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	10 Sep 2020 22:30:26

US3432023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 22:30:26

US3432023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Sep 2020 11:34:47

US3432023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Phoebe Cunningham (b) (4)	12 Sep 2020 11:34:47

US3432023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	12 Sep 2020 11:34:47

US3432023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	12 Sep 2020 11:34:47

US3432023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Sep 2020 11:34:52

US3432023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 11:34:52

US3432023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	17 Sep 2020 14:52:49

US3432023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Phoebe Cunningham (b) (4)	17 Sep 2020 14:52:49

US3432023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	17 Sep 2020 14:52:49

US3432023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	17 Sep 2020 14:52:49

US3432023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:31:22

US3432023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 15:31:22

US3432023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:41:37

US3432023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 15:41:37

US3432023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Sep 2020 15:41:37

US3432023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:41:37

US3432023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:42:56

US3432023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 15:42:56

US3432023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexander Mills (b) (4) (b) (4)	01 Oct 2020 20:12:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '01 Oct 2020'	Alexander Mills (b) (4) (b) (4)	01 Oct 2020 20:12:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Alexander Mills (b) (4)	01 Oct 2020 20:12:36
	(b) (4)	

US3432023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	01 Oct 2020 20:12:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexander Mills (b) (4)	01 Oct 2020 20:13:36
	(b) (4)	

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Oct 2020'	Alexander Mills (b) (4) (b) (4)	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '15:17'	Alexander Mills (b) (4) (b) (4)	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '01 Oct 2020 15:17'	System	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.6' F	Alexander Mills (b) (4)	01 Oct 2020 20:13:36
	(b) (4)	

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Alexander Mills (b) (4) (b) (4)	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alexander Mills (b) (4)	01 Oct 2020 20:13:36
	(b) (4)	

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	Alexander Mills (b) (4) (b) (4)	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '12'	Alexander Mills (b) (4) (b) (4)	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '124'	Alexander Mills (b) (4) (b) (4)	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '61'	Alexander Mills (b) (4) (b) (4)	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 20:13:36

US3432023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	01 Oct 2020 20:18:14
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	01 Oct 2020 20:17:55
User entered 'No (N)'	Alexander Mills (b) (4) (b) (4)	01 Oct 2020 20:17:55

US3432023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Alexander Mills (b) (4)	01 Oct 2020 20:18:14
User entered '01 Oct 2020'	Alexander Mills (b) (4)	01 Oct 2020 20:17:55

US3432023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:32:37

US3432023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '01 Oct 2020'	Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:32:37

US3432023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '15:44'	Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:32:37

US3432023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '01 Oct 2020 15:44'	System	01 Oct 2020 20:32:37

US3432023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:32:46

US3432023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 20:32:46

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 92'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-06T15:12:48', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'e870f24d-cabf-44c5-bff8-da543d80dde9' User entered 'No (N)'	System	06 Nov 2020 20:13:55
	System	06 Nov 2020 20:13:55

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-06T15:12:59', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'e870f24d-cabf-44c5-bff8-da543d80dde9' User entered 'Yes (Y)'	System	06 Nov 2020 20:13:55

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Please 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-06T15:13:13', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'e870f24d-cabf-44c5-bff8-da543d80dde9'	System	06 Nov 2020 20:13:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Nov 2020 20:13:55

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-06T15:13:42', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'e870f24d-cabf-44c5-bff8-da543d80dde9' User entered '06 Nov 2020 15:13:42'	System	06 Nov 2020 20:13:55
	System	06 Nov 2020 20:13:55

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered '02 Nov 2020 00:01'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered '06 Nov 2020 23:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered 'Day 106'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-16T13:49:02', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'bdb15c31-671f-4c64-8752-803aa84c38d2'	System	16 Nov 2020 18:49:21
User entered 'No (N)'	System	16 Nov 2020 18:49:21

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-16T13:49:08', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'bdb15c31-671f-4c64-8752-803aa84c38d2'	System	16 Nov 2020 18:49:21
User entered 'No (N)'	System	16 Nov 2020 18:49:21

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-16T13:49:18', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: 'bdb15c31-671f-4c64-8752-803aa84c38d2' User entered '16 Nov 2020 13:49:18'	System	16 Nov 2020 18:49:21
	System	16 Nov 2020 18:49:21

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered '16 Nov 2020 00:01'	System	05 Aug 2020 18:03:29

US3432023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 18:03:29
User entered '20 Nov 2020 23:59'	System	05 Aug 2020 18:03:29

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '02 Oct 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '06 Oct 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '09 Oct 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '13 Oct 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '16 Oct 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '20 Oct 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '23 Oct 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '27 Oct 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '30 Oct 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '03 Nov 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '06 Nov 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '10 Nov 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '13 Nov 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '17 Nov 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-22T10:22:16', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '434d9544-067e-4dd1-8422-be7a7c1a714b'	System	22 Nov 2020 15:22:37
User entered 'No (N)'	System	22 Nov 2020 15:22:37

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

Have you been exposed to someone with 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 (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-22T10:22:25', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '434d9544-067e-4dd1-8422-be7a7c1a714b'	System	22 Nov 2020 15:22:37
User entered 'No (N)'	System	22 Nov 2020 15:22:37

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3751B129-5897-434D-9E7A-220A36DB957B)', Time: '2020-11-22T10:22:34', User OID: 'PatientReportedOutcome (US3432023)', ODM File OID: '434d9544-067e-4dd1-8422-be7a7c1a714b' User entered '22 Nov 2020 10:22:34'	System	22 Nov 2020 15:22:37
	System	22 Nov 2020 15:22:37

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 13:27:06

US3432023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:27:06
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 13:27:06

US3432023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 17:24:49

US3432023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 17:24:49

US3432023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Oct 2020 17:24:49

US3432023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 17:24:49

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:25:41

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '7 Aug 2020'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 18:59:41

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:25:41

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '11:00'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 18:59:41

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:25:41

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '7 Aug 2020 11:00'	System	07 Aug 2020 18:59:41

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:25:41

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Monica Feeley (b) (4)	07 Aug 2020 18:59:41

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:25:41

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 18:59:41

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:53:51
User entered 'Day 1 (Day 1)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[Date](#)

Audit	User	Time (GMT)
User entered '7 Aug 2020'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[Temperature](#)

Audit	User	Time (GMT)
User entered '37.0' C	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:25:41

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	07 Aug 2020 19:02:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:53:51
User entered 'Day 2 (Day 2)'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[Date](#)

Audit	User	Time (GMT)
User entered '8 Aug 2020'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[Temperature](#)

Audit	User	Time (GMT)
User closed query 'Per DM: Please review source and confirm 98.4 C is correct. If not correct, please update.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 14:18:48
Query 'Per DM: Please review source and confirm 98.4 C is correct. If not correct, please update.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	19 Aug 2020 19:21:31
User entered '98.4' F reason for change: Per Query Resolution	Monica Feeley (b) (4)	19 Aug 2020 19:21:24
User opened query 'Per DM: Please review source and confirm 98.4 C is correct. If not correct, please update.' (Site from DM).	(b) (4), (b) (6)	13 Aug 2020 09:10:13
User entered '98.4' C	Monica Feeley (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:25:41

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	08 Aug 2020 17:52:28

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:53:51
User entered 'Day 3 (Day 3)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[Date](#)

Audit	User	Time (GMT)
User entered '9 Aug 2020'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.6' F	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:25:41

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:32

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:53:51
User entered 'Day 4 (Day 4)'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[Date](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

Fatigue

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:25:41

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Aug 2020 11:11:58

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:53:51
User entered 'Day 5 (Day 5)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[Date](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.2' F	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:25:41

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:40:48

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:53:51
User entered 'Day 6 (Day 6)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[Date](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:25:41

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:04

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[Date](#)

Audit	User	Time (GMT)
User entered '6 Aug 2020'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:25:41

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 18:54:20

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:25:41

[Date of Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: GCL has Saliva Day 3, dated 09AUG2020; however there is no Saliva Log completed. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 04:45:36
Query 'Per GCL Lab Recon: GCL has Saliva Day 3, dated 09AUG2020; however there is no Saliva Log completed. Please reconcile or clarify' answered with 'Updated' (Site from DM).	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:50:55
User opened query 'Per GCL Lab Recon: GCL has Saliva Day 3, dated 09AUG2020; however there is no Saliva Log completed. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 14:24:33
User entered '7 Aug 2020'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:51

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:25:41

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User closed query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 07 AUG 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 03:32:30
Query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 07 AUG 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'Updated' (Site from DM).	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:51:06
User opened query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 07 AUG 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 04:18:34
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:51

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:25:41

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:51

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:25:41

[Date of Test](#)

Audit	User	Time (GMT)
User entered '7 Aug 2020'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:51

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:25:41

[Type of Test Performed](#)

Audit	User	Time (GMT)
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:51

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:25:41

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:51

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:25:41

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4)	16 Sep 2020 21:26:23
Amendment Manager inserted this DataPoint.	(b) (4) System	21 Aug 2020 02:15:11

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:25:41

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:22:51

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:25:41

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Monica Feeley (b) (4)	16 Sep 2020 21:26:23
User entered 'Yes (Y)'	Monica Feeley (b) (4)	19 Aug 2020 19:22:51

US3432023

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:25:41

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '0'	System	21 Aug 2020 02:15:14
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:15:11

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:25:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:25:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:25:41

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:25:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:25:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:25:41

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:25:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:25:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:25:41

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:25:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:25:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:25:41

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:25:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:25:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:25:41

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:25:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:25:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:25:41

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:25:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:25:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:25:41

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jun Bai Park Chang (b) (4)	10 Nov 2020 22:37:21

US3432023

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:54:59

US3432023

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '7 Aug 2020'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:54:59

US3432023

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:54:59

US3432023

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	10 Nov 2020 21:54:59

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Aug 2020'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '11:47'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '7 Aug 2020 11:47'	System	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jun Bai Park Chang	10 Nov 2020 21:55:38
DataPoint set to visible.	(b) (4) System	10 Nov 2020 21:54:59

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jun Bai Park Chang	10 Nov 2020 21:55:38
DataPoint set to visible.	(b) (4) System	10 Nov 2020 21:54:59

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37' C	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '58'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '16'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '138'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '63'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Nov 2020 21:55:38

US3432023

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:53

US3432023

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '7 Aug 2020'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:55:53

US3432023

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:25:41

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:56:12

US3432023

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:25:41

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '7 Aug 2020'	Jun Bai Park Chang (b) (4)	10 Nov 2020 21:56:12

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:25:41

[Visit Date](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	10 Nov 2020 15:35:57
User entered '7 Aug 2020'	Monica Feeley (b) (4)	19 Aug 2020 19:19:43

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:25:41

[Physical Exam](#)

Audit	User	Time (GMT)
User entered '1'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:19:43

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:25:41

[Vital Signs](#)

Audit	User	Time (GMT)
User entered '1'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:19:43

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:25:41

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
User entered '1'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:19:43

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:25:41

[Pregnancy Test](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:19:43

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:20:34

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '7 Aug 2020'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:20:34

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '11:47'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:20:34

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '7 Aug 2020 11:47'	System	19 Aug 2020 19:20:34

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.0' C	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:20:34

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:20:34

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:20:34

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '058'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:20:34

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Aug 2020 19:20:34

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '016'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:20:34

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Aug 2020 19:20:34

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please confirm clinical significance on high blood pressure, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:26:20
Query 'Per ETRTR: Please confirm clinical significance on high blood pressure, thanks.' answered with 'not clinically significant' (Site from CRA).	Monica Feeley (b) (4)	27 Aug 2020 11:18:09
User opened query 'Per ETRTR: Please confirm clinical significance on high blood pressure, thanks.' (Site from CRA).	(b) (4), (b) (6)	21 Aug 2020 14:56:17
User entered '138'	Monica Feeley (b) (4)	19 Aug 2020 19:20:34

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 19:20:34

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '063'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:20:34

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 19:20:34

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:21:08

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Aug 2020'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:21:08

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 07Aug2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail.' answered with 'PPD reports they received samples (Illness D1 [1]).' (Site from DM).	Jun Bai Park Chang (b) (4)	10 Nov 2020 14:13:47
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 07Aug2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 17:35:12
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:20:02

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '7 Aug 2020'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:20:02

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '12:07'	Monica Feeley (b) (4) (b) (4)	19 Aug 2020 19:20:02

US3432023

Folder: Unscheduled 07 Aug 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
User entered '7 Aug 2020 12:07'	System	19 Aug 2020 19:20:02

US3432023

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:25:41

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 14:21:23
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:30:38

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:02:54
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:36:30
User entered 'USA-US078-2020-mRNA-1273-P301000001'	System	21 Aug 2020 13:36:22
User entered 'New'	(b) (4), (b) (6)	21 Aug 2020 13:36:22

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 12:24:38
User closed query 'PV Query: Please consider updating the event term to the final/underlying diagnosis, when available.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 12:33:30
Query 'PV Query: Please consider updating the event term to the final/underlying diagnosis, when available.' answered with 'this is the underlying diagnosis as of now' (Site from Safety).	Monica Feeley (b) (4)	16 Sep 2020 21:03:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Connective tissue disorders (excl congenital), HLT: Connective tissue disorders NEC, PT: Polymyalgia rheumatica, LLT: Polymyalgia rheumatica - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 10:55:58
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 10:55:58
User opened query 'PV Query: Please consider updating the event term to the final/underlying diagnosis, when available.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 14:20:34
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event if identified.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 13:33:02
Data point term sent to Coder	System	26 Aug 2020 21:32:01
Coding entries removed.	Monica Feeley (b) (4)	26 Aug 2020 21:31:16
User entered 'Possible Polymyalgia rheumatica' reason for change: New Information	Monica Feeley (b) (4)	26 Aug 2020 21:31:16
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event if identified.' answered with 'etiology still unknown, event term staying as weakness for now' (Site from Safety).	Monica Feeley (b) (4)	25 Aug 2020 21:38:14
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event if identified.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:18:28
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Asthenia, LLT: Weakness - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 21:41:23

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	20 Aug 2020 21:41:23
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 21:41:03
User entered 'Weakness'	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52
	(b) (4)	

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:02:59
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:03:02
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:03:04
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 21:17:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 21:17:31
User entered 'No (N)' reason for change: Per Query Resolution	Monica Feeley (b) (4)	21 Aug 2020 21:17:31
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 13:36:22
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:36:22
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:15:11

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:03:05
User entered '20 Aug 2020'	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52
	(b) (4)	

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 12:24:46
User entered empty.	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52
	(b) (4)	

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 12:24:48
User closed query 'Per ETRTR: Please confirm and update reponse if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:29:59
Query 'Per ETRTR: Please confirm and update reponse if applicable, thanks.' answered with 'condition ongoing' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	25 Aug 2020 21:37:00
User opened query 'Per ETRTR: Please confirm and update reponse if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Aug 2020 15:38:08
Query 'Per ETRTR: Please confirm an update reponse if applicable, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	24 Aug 2020 15:37:39
User opened query 'Per ETRTR: Please confirm an update reponse if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Aug 2020 15:37:36
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition), then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 16:24:55
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 16:24:47
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 21:34:42
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:42:39
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' answered with 'not available, not likely to resolve' (Site from Safety). DataPoint Verified.	Monica Feeley (b) (4)	21 Oct 2020 14:28:34
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 13:06:44
User closed query 'PV Query: Please provide the end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 13:27:48
User closed query 'PV Query: Please provide the end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 17:36:17

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'not available yet' (Site from Safety).	Monica Feeley (b) (4)	23 Sep 2020 22:17:17
User opened query 'PV Query: Please provide the end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:51:47
Query '20200922_US3432023_MOD-2020-000211_FU2_MedReview' canceled (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:51:00
User opened query '20200922_US3432023_MOD-2020-000211_FU2_MedReview' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:50:58
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 12:33:34
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'not available yet' (Site from Safety).	Monica Feeley (b) (4)	16 Sep 2020 21:03:28
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 14:20:04
User entered empty.	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 13:06:49
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 13:41:28
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'condition ongoing' (Site from Safety).	Monica Feeley (b) (4)	25 Aug 2020 21:37:06
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:18:23
User entered empty.	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:03:34
User entered 'Grade 3/Severe (Grade 3/Severe)'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:03:36
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:03:41
User entered '0'	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52
	(b) (4)	

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:03:43
User entered '0'	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52
	(b) (4)	

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:03:44
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	21 Aug 2020 12:16:32
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'has not been discharged' (Site from System).	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:41:21
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	20 Aug 2020 21:40:52
User entered '1'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:03:46
User entered '20 Aug 2020'	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52
	(b) (4)	

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please confirm and update reponse if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:30:06
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:52
User closed query 'PV Query: Please add the hospital discharge date here as reported in the narrative below.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 13:33:24
Query 'Per ETRTR: Please confirm and update reponse if applicable, thanks.' answered with 'updated response' (Site from CRA).	Monica Feeley (b) (4)	25 Aug 2020 21:22:21
Query 'PV Query: Please add the hospital discharge date here as reported in the narrative below.' answered with 'updated with hospital discharge date' (Site from Safety).	Monica Feeley (b) (4)	25 Aug 2020 21:22:08
User entered '21 Aug 2020' reason for change: Per Query Resolution	Monica Feeley (b) (4)	25 Aug 2020 21:21:37
User opened query 'PV Query: Please add the hospital discharge date here as reported in the narrative below.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:18:18
User opened query 'Per ETRTR: Please confirm and update reponse if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Aug 2020 15:38:26
User entered empty.	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:54
User entered 'No (N)'	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52
	(b) (4)	

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:55
User entered empty.	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52
	(b) (4)	

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:57
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:59
User entered '0'	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52
	(b) (4)	

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:20:01
User entered '0'	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52
	(b) (4)	

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:20:03
User entered 'Related (RELATED)' reason for change: New Information	Monica Feeley (b) (4)	26 Aug 2020 21:31:16
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:21:08
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'CDM RQ: Per previous query, please complete the Dosing Discontinuation page in End of Study folder to reflect this action taken.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 04:39:13
Query 'CDM RQ: Per previous query, please complete the Dosing Discontinuation page in End of Study folder to reflect this action taken.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	14 Oct 2020 22:15:24
User opened query 'CDM RQ: Per previous query, please complete the Dosing Discontinuation page in End of Study folder to reflect this action taken.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 15:17:44
User closed query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 15:17:44
Query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' answered with 'It is unclear what this query is asking. Per protocol, participant cannot receive further dosing of product. Therefore, we terminated his treatment and he did not receive second dose. The most appropriate choice for "action taken with investigational product" is "investigational product withdrawn," which is reflected here.' (Site from DM).	Monica Feeley (b) (4)	23 Sep 2020 20:42:32
User opened query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:53:00
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:21:10
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	Monica Feeley (b) (4)	26 Aug 2020 21:34:10
User entered 'None (NONE)'	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:21:14
User entered '0' reason for change: New Information	Monica Feeley (b) (4)	26 Aug 2020 21:32:53
User entered '1'	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:21:17
User entered '1' reason for change: New Information	Monica Feeley (b) (4)	26 Aug 2020 21:32:53
User entered '0'	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:21:19
User entered '0'	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52
	(b) (4)	

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until a final diagnosis and plan for long-term treatment and follow-up for the event has been established.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 16:24:32
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 16:24:26
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 21:34:30
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 20:16:20
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'not available, not like to resolve' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	21 Oct 2020 14:28:22
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:53:28
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 12:33:42

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'not sure if any resolution. Will update information if there is an outcome?' (Site from Safety). DataPoint Verified.	Monica Feeley (b) (4) (b) (4)	16 Sep 2020 21:06:36
	(b) (4), (b) (6)	04 Sep 2020 15:21:21
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	27 Aug 2020 13:33:07
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:18:14
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	21 Aug 2020 22:24:07
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	21 Aug 2020 22:24:07
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Xhoi Mitre (b) (4) (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:21:25
User entered empty; reason for change New Information	Monica Feeley (b) (4)	27 Aug 2020 13:33:07
User entered 'N/A' reason for change: New Information	Monica Feeley (b) (4)	21 Aug 2020 22:24:07
User entered empty.	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm that the subject did not receive any vaccines for 6 months prior to study entry.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 15:01:52
Query 'PV Query: Please confirm that the subject did not receive any vaccines for 6 months prior to study entry.' answered with 'subject did not receive any vaccines for 6 months prior to study entry ' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 13:40:58
User opened query 'PV Query: Please provide office visit notes and laboratory results from subject's follow-up visits with Rheumatology to Safety_Moderna@iqvia.com when available. Please leave query open/unanswered until able to obtain and send records.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 21:35:14
User opened query 'PV Query: Please confirm that the subject did not receive any vaccines for 6 months prior to study entry.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 21:34:56
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 13:07:00
User closed query 'PV Query: In either the Rheumatology consultation notes or other outpatient/inpatient medical records – is there documentation stating the relatedness of the participant's symptoms to study vaccination and justification for the relatedness?' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:42:36
User closed query 'PV Query: In either the Rheumatology consultation notes or outpatient/inpatient medical records -- is the diagnosis "possible PMR" or "PMR"?' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:42:35
User closed query 'PV Query: Why did the participant have a chest CT on 10-Aug (prior to presenting to the ER with marked sx's of PMR)?' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:42:31
User closed query 'PV Query: The 10-Aug chest CT shows "near complete resolution" of GGO, indicating (?) previous infection. 1. Please provide the date of the chest CT performed previous to 10-Aug 2. Please provide the participant's diagnosis the time of this previous chest CT' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:42:29

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: The records available state that the participant reported a flare of low back pain 2 days prior to enrollment/1st dose. 1. Is this event documented in the study site record at enrollment? 2. Is this event documented in the medical records? 3. If yes to either, please provide this documentation. [Note -- Medwatch report 15-day f/u summary -- “back pain and possibly myalgias might have been noted” -- if these symptoms were documented in the study site records/medical records, state that they were documented]' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:42:27
User closed query 'PV Query: Did the participant receive any vaccinations within the 6 months prior to study entry? If yes, please provide the date and type of vaccination.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:42:25
User closed query 'PV Query: What is the status of the participant's MGUS? Please provide the 3 most recent HemeOnc consult clinic records.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:42:24
User closed query 'PV Query: What is the etiology of the participant's hypothyroidism (eg Grave's disease vs other etiology)?' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:42:22
User closed query 'PV Query: Please provide further details of the clinical course to resolution.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:42:20
Query 'PV Query: In either the Rheumatology consultation notes or other outpatient/inpatient medical records – is there documentation stating the relatedness of the participant's symptoms to study vaccination and justification for the relatedness?' answered with 'Rheum discusses possible PMR may be related to vaccine. Will send redacted note' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 22:13:12

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: The records available state that the participant reported a flare of low back pain 2 days prior to enrollment/1st dose. 1. Is this event documented in the study site record at enrollment? 2. Is this event documented in the medical records? 3. If yes to either, please provide this documentation. [Note -- Medwatch report 15-day f/u summary -- "back pain and possibly myalgias might have been noted" -- if these symptoms were documented in the study site records/medical records, state that they were documented]' answered with 'Medical history obtained at screening visit noted: chronic lower back pain with intermittent flare. Note in binder from 26UAG2020 states: at time of enrollment, pt felt well. However, in retrospect, pt thinks they may have had back pain few days before IP. Mild and though related to chronic back pain' (Site from Safety).	Monica Feeley (b) (4)	14 Oct 2020 22:12:16
Query 'PV Query: Did the participant receive any vaccinations within the 6 months prior to study entry? If yes, please provide the date and type of vaccination.' answered with 'no vaccines noted in medical record. We will have to follow up with participant to confirm' (Site from Safety).	Monica Feeley (b) (4)	14 Oct 2020 22:07:23
Query 'PV Query: Please provide further details of the clinical course to resolution.' answered with 'Participant currently tapering prednisone. Patient currently on 15 mg prednisone daily. Participant reports they feel good. However, condition has not ended. Participant following up with Rheum for speed of taper as well as overall condition.' (Site from Safety).	Monica Feeley (b) (4)	14 Oct 2020 22:05:31
Query 'PV Query: What is the etiology of the participant's hypothyroidism (eg Grave's disease vs other etiology)?' answered with 'Medical record states "unspecified type" of hypothyroidism' (Site from Safety).	Monica Feeley (b) (4)	14 Oct 2020 21:16:36
Query 'PV Query: In either the Rheumatology consultation notes or outpatient/inpatient medical records -- is the diagnosis "possible PMR" or "PMR"? answered with 'in the consultation notes, it is possible PMR.' (Site from Safety).	Monica Feeley (b) (4)	14 Oct 2020 21:14:38

v6.020 DTW (1102)

1712 of 2162

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: The 10-Aug chest CT shows “near complete resolution” of GGO, indicating (?) previous infection. 1. Please provide the date of the chest CT performed previous to 10-Aug 2. Please provide the participant’s diagnosis the time of this previous chest CT' answered with 'Previous date of CT: 07MAY2019. Diagnosis at time was pulmonary edema because of aortic stenosis. ' (Site from Safety).	Monica Feeley (b) (4)	14 Oct 2020 21:13:29
Query 'PV Query: What is the status of the participant’s MGUS? Please provide the 3 most recent HemeOnc consult clinic records.' answered with 'Pt saw heme/onc many years ago. Was told no follow up necessary. no notes available from appointment. Currently followed by internist. Last immunofixation 17APR2020 showed no monoclonal band.' (Site from Safety).	Monica Feeley (b) (4)	14 Oct 2020 21:06:49
Query 'PV Query: Why did the participant have a chest CT on 10-Aug (prior to presenting to the ER with marked sx of PMR)?' answered with 'Participant has history of pulmonary nodules. This was a follow up exam/CT for monitoring the nodules. ' (Site from Safety).	Monica Feeley (b) (4)	14 Oct 2020 19:19:10
User opened query 'PV Query: In either the Rheumatology consultation notes or other outpatient/inpatient medical records – is there documentation stating the relatedness of the participant’s symptoms to study vaccination and justification for the relatedness?' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:46:30
User opened query 'PV Query: In either the Rheumatology consultation notes or outpatient/inpatient medical records -- is the diagnosis “possible PMR” or “PMR”?' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:46:19
User opened query 'PV Query: The 10-Aug chest CT shows “near complete resolution” of GGO, indicating (?) previous infection. 1. Please provide the date of the chest CT performed previous to 10-Aug 2. Please provide the participant’s diagnosis the time of this previous chest CT' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:46:03

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Why did the participant have a chest CT on 10-Aug (prior to presenting to the ER with marked sx's of PMR)?' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:45:47
User opened query 'PV Query: The records available state that the participant reported a flare of low back pain 2 days prior to enrollment/1st dose. 1. Is this event documented in the study site record at enrollment? 2. Is this event documented in the medical records? 3. If yes to either, please provide this documentation. [Note -- Medwatch report 15-day f/u summary -- "back pain and possibly myalgias might have been noted" -- if these symptoms were documented in the study site records/medical records, state that they were documented]' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:45:28
User opened query 'PV Query: Did the participant receive any vaccinations within the 6 months prior to study entry? If yes, please provide the date and type of vaccination.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:45:14
User opened query 'PV Query: What is the status of the participant's MGUS? Please provide the 3 most recent HemeOnc consult clinic records.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:45:02
User opened query 'PV Query: What is the etiology of the participant's hypothyroidism (eg Grave's disease vs other etiology)?' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:44:51
User opened query 'PV Query: Please provide further details of the clinical course to resolution.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 13:28:14
Query 'Please provide further details of the clinical course to resolution. Please keep query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 13:28:07
User closed query 'PV Query: Please confirm if the subject started prednisone again on 09 Sep (per narrative) or 11 Sep (per CM eCRF). ' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 17:38:06
User closed query 'PV Query: Please add sulfa and barbiturate allergies, chronic kidney disease stage 3b/4 to MH, as reported in discharge summary.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 17:38:03

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative contains medications. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 15:59:05
Query 'PV Query: Please add sulfa and barbiturate allergies, chronic kidney disease stage 3b/4 to MH, as reported in discharge summary.' answered with 'After his discharge summary was received by our site, a study physician called participant to discuss additional medical history and concomitant medications that were found in his record. We rely on participant's verbal medical history and concomitant medications. It is our best practice to trust the participant. Per the conversation the physician had with the participant, all medical history and medication relayed by the participant has been recorded and we updated the source docs and eCRFs. Anything not recorded has been omitted by the participant's verbal communication with us. Physician followed up on all items and participant confirmed the items listed and denied the items not listed.' (Site from Safety).	Monica Feeley (b) (4)	23 Sep 2020 20:48:00
Query 'Per DM CLR: SAE Narrative contains medications. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies.' answered with 'prednisone is recorded in the proper eCRFs (see concomitant medications)' (Site from DM).	Monica Feeley (b) (4)	23 Sep 2020 20:38:49
Query 'PV Query: Please confirm if the subject started prednisone again on 09 Sep (per narrative) or 11 Sep (per CM eCRF). ' answered with 'he went to rheum on 09SEP2020. He started on 11SEP2020 per CM eCRF' (Site from Safety).	Monica Feeley (b) (4)	23 Sep 2020 20:38:04
User opened query 'Per DM CLR: SAE Narrative contains medications. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:52:32

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Please provide further details of the clinical course to resolution. Please keep query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:52:28
User opened query 'PV Query: Please confirm if the subject started prednisone again on 09 Sep (per narrative) or 11 Sep (per CM eCRF). ' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:50:06
User opened query 'PV Query: Please add sulfa and barbiturate allergies, chronic kidney disease stage 3b/4 to MH, as reported in discharge summary.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:49:31
Query '20200922_US3432023_MOD-2020-000211_FU2_MedReview' canceled (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:48:44
User opened query '20200922_US3432023_MOD-2020-000211_FU2_MedReview' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:48:42
Query '20200922_US3432023_MOD-2020-000211_FU2_MedReview' canceled (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:48:34
User opened query '20200922_US3432023_MOD-2020-000211_FU2_MedReview' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 20:48:33
User closed query 'PV Query: Please confirm if a COVID test was performed at the hospital and provide results, if applicable. ' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 12:33:57
User closed query 'PV Query: Please provide further details of the clinical course to resolution.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 12:33:52
User closed query 'PV Query. Please provide date, units and reference ranges for the reported laboratory testing of CRP and ESR if available. If unavailable, please state as such.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 12:33:49
User closed query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted, when available.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 12:33:45

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
User entered '24AUG20, WE RECEIVED RHEUMATOLOGY ATTENDING CONSULTATION NOTE WHO SAW PT 21AUG20 AT HOSPITAL. SPOKE W/ RHEUMATOLOGIST TO DISCUSS CASE IN DETAIL. AT TIME OF ENROLLMENT PT FELT WELL. HOWEVER, PT NOTED HE MAY HAVE STARTED TO HAVE BACK PAIN A FEW DAYS BEFORE RECEIVING IP. SYMPTOMS AT THAT TIME WERE MILD & THOUGHT TO BE RELATED TO HIS CHRONIC BACK PAIN. HE RECEIVED IP ON 5AUG20 & REPORTED INCREASED BACK PAIN OVER THE NEXT DAYS & PROGRESSIVELY DEVELOPED MIGRATORY MYALGIAS (BACK, SHOULDERS, OCCIPUT, PARASPINAL MUSCLES) & WEAKNESS. DENIED ANY LOCAL INJECTION SITE REACTION AFTER VACCINATION. THE MYALGIAS BECAME SEVERE 20AUG20, & HE WAS NOT ABLE TO GET OF OUT BED BECAUSE OF GENERALIZED WEAKNESS. HE WAS HOSPITALIZED BETWEEN 20AUG20 AND 21AUG20. WORK-UP 20AUG20 NOTABLE FOR CRP AT 96.9 MG/L (REF 0.0-5.0) AND ESR AT 56 MM/H (REF 0-15). HE RECEIVED 15 MG OF PREDNISONE ON 20AUG20. FELT MUCH BETTER 21AUG20 & DISCHARGED W/ PRESCRIPTION OF PREDNISONE 20 MG DAILY, WITH A PLANNED TAPERING OVER 16 DAYS. AT THIS TIME RHEUMATOLOGIST THINKS PMR MAY BE POSSIBLE DIAGNOSIS. BACK PAIN PRESENT BEFORE THE IP ADMINISTRATION, BUT POLYMYALGIA AND WEAKNESS DEVELOPED AFTER VACCINE ADMINISTRATION. WE ARE UPDATING AE TO INCLUDE ADDITIONAL SYMPTOMS. GIVEN THIS ADDITIONAL INFORMATION, THE CONSULTATION WITH THE TREATING RHEUMATOLOGIST, & TIMING OF DEVELOPMENT OF THESE SYMPTOMS IT IS POSSIBLE THAT VACCINE MAY HAVE	Monica Feeley (b) (4) (b) (4)	16 Sep 2020 21:38:06

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
CONTRIBUTED TO THE SYMPTOMS. THUS, WE ARE CHANGING OUR ASSESSMENT THAT THERE MAY BE A POSSIBLE RELATIONSHIP BETWEEN THE SYMPTOMATOLOGY OF PT AND THE STUDY PRODUCT. AS OF TODAY HE FEELS GOOD DURING THE DAY, BUT WAKES UP IN MORNING WITH SOME PAIN IN THE SHOULDERS AND NECK. THE PAIN GOES AWAY APPROXIMATELY 2 HOURS AFTER TAKING THE 20 MG DOSE OF PREDNISONE. HE REMAINS IN CLOSE CONTACT WITH HIS RHEUMATOLOGIST.COVID TEST 20AUG20-NEGATIVE Pt felt better w/ prednisone. Off prednisone around 4SEP20 w/ recurrence of axial myalgias. Went to rheum 9SEP20. On 20mg prednisone for 2 weeks then slow taper' reason for change: New Information Query 'PV Query: Please provide further details of the clinical course to resolution.' answered with 'we will provide updates for management' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	16 Sep 2020 21:19:51

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
User entered '24AUG20, WE RECEIVED CONSULTATION NOTE OF RHEUMATOLOGY ATTENDING WHO SAW PT 21AUG20 AT FAULKNER HOSPITAL. WE SPOKE WITH RHEUMATOLOGIST TO DISCUSS CASE IN DETAIL. AT TIME OF ENROLLMENT PT FELT WELL. HOWEVER, PT NOTED THAT HE MAY HAVE STARTED TO HAVE BACK PAIN A FEW DAYS BEFORE RECEIVING THE IP. THE SYMPTOMS AT THAT TIME WERE MILD AND THOUGHT TO BE RELATED TO HIS CHRONIC BACK PAIN. HE RECEIVED THE IP ON 5AUG20 AND REPORTED INCREASED BACK PAIN OVER THE NEXT DAYS AND HE PROGRESSIVELY DEVELOPED MIGRATORY MYALGIAS (BACK, SHOULDERS, OCCIPUT, PARASPINAL MUSCLES) AND WEAKNESS. HE DENIED ANY LOCAL INJECTION SITE REACTION AFTER VACCINATION. THE MYALGIAS BECAME SEVERE ON 20AUG20, AND HE WAS NOT ABLE TO GET OF OUT BED BECAUSE OF GENERALIZED WEAKNESS. HE WAS HOSPITALIZED BETWEEN 20AUG20 AND 21AUG20. WORK-UP 20AUG20 NOTABLE FOR CRP AT 96.9 MG/L (REF 0.0-5.0) AND ESR AT 56 MM/H (REF 0-15). HE RECEIVED 15 MG OF PREDNISONE ON 20AUG20. FELT MUCH BETTER ON 21AUG20 AND DISCHARGED WITH PRESCRIPTION OF PREDNISONE 20 MG DAILY, WITH A PLANNED TAPERING OVER 16 DAYS. AT THIS TIME RHEUMATOLOGIST THINKS PMR MAY BE POSSIBLE DIAGNOSIS. BACK PAIN WAS PRESENT BEFORE THE IP ADMINISTRATION, BUT POLYMYALGIA AND WEAKNESS DEVELOPED AFTER VACCINE ADMINISTRATION. WE ARE UPDATING ADVERSE EVENT TO INCLUDE THESE ADDITIONAL SYMPTOMS. GIVEN THIS ADDITIONAL INFORMATION, THE CONSULTATION WITH THE TREATING	Monica Feeley (b) (4) (b) (4)	16 Sep 2020 21:18:49

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
RHEUMATOLOGIST, AND THE TIMING OF THE DEVELOPMENT OF THESE SYMPTOMS IT IS POSSIBLE THAT THE VACCINE MAY HAVE CONTRIBUTED TO THE SYMPTOMS. THUS, WE ARE CHANGING OUR ASSESSMENT THAT THERE MAY BE A POSSIBLE RELATIONSHIP BETWEEN THE SYMPTOMATOLOGY OF PT AND THE STUDY PRODUCT. AS OF TODAY HE FEELS GOOD DURING THE DAY, BUT WAKES UP IN MORNING WITH SOME PAIN IN THE SHOULDERS AND NECK. THE PAIN GOES AWAY APPROXIMATELY 2 HOURS AFTER TAKING THE 20 MG DOSE OF PREDNISONE. HE REMAINS IN CLOSE CONTACT WITH HIS RHEUMATOLOGIST. WE CONTINUE TO FOLLOW PT CLOSELY. COVID test 20AUG2020- negative' reason for change: New Information		
Query 'PV Query: Please confirm if a COVID test was performed at the hospital and provide results, if applicable. ' answered with 'tested at hospital 20AUG2020. negative. ' (Site from Safety).	Monica Feeley (b) (4)	16 Sep 2020 21:14:01
Query 'PV Query. Please provide date, units and reference ranges for the reported laboratory testing of CRP and ESR if available. If unavailable, please state as such.' answered with 'date, units and reference ranges updated.)CRP AT 96.9 MG/L (REF 0.0-5.0) AND ESR AT 56 MM/H (REF 0-15).)' (Site from Safety).	Monica Feeley (b) (4)	16 Sep 2020 21:12:47
DataPoint Un-verified.	Monica Feeley (b) (4)	16 Sep 2020 21:11:50

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
User entered '24AUG20, WE RECEIVED CONSULTATION NOTE OF RHEUMATOLOGY ATTENDING WHO SAW PT 21AUG20 AT FAULKNER HOSPITAL. WE SPOKE WITH RHEUMATOLOGIST TO DISCUSS CASE IN DETAIL. AT TIME OF ENROLLMENT PT FELT WELL. HOWEVER, PT NOTED THAT HE MAY HAVE STARTED TO HAVE BACK PAIN A FEW DAYS BEFORE RECEIVING THE IP. THE SYMPTOMS AT THAT TIME WERE MILD AND THOUGHT TO BE RELATED TO HIS CHRONIC BACK PAIN. HE RECEIVED THE IP ON 5AUG20 AND REPORTED INCREASED BACK PAIN OVER THE NEXT DAYS AND HE PROGRESSIVELY DEVELOPED MIGRATORY MYALGIAS (BACK, SHOULDERS, OCCIPUT, PARASPINAL MUSCLES) AND WEAKNESS. HE DENIED ANY LOCAL INJECTION SITE REACTION AFTER VACCINATION. THE MYALGIAS BECAME SEVERE ON 20AUG20, AND HE WAS NOT ABLE TO GET OF OUT BED BECAUSE OF GENERALIZED WEAKNESS. HE WAS HOSPITALIZED BETWEEN 20AUG20 AND 21AUG20. WORK-UP 20AUG20 NOTABLE FOR CRP AT 96.9 mg/L (ref 0.0-5.0) AND ESR AT 56 mm/h (ref 0-15). HE RECEIVED 15 MG OF PREDNISONE ON 20AUG20. HE FELT MUCH BETTER ON 21AUG20 AND WAS DISCHARGED WITH A PRESCRIPTION OF PREDNISONE 20 MG DAILY, WITH A PLANNED TAPERING OVER 16 DAYS. AT THIS TIME THE RHEUMATOLOGIST THINKS THAT PMR MAY BE A POSSIBLE DIAGNOSIS. BACK PAIN WAS PRESENT BEFORE THE IP ADMINISTRATION, BUT THE POLYMYALGIA AND THE WEAKNESS DEVELOPED AFTER THE VACCINE ADMINISTRATION. WE ARE UPDATING THIS ADVERSE EVENT TO INCLUDE THESE ADDITIONAL SYMPTOMS. GIVEN THIS ADDITIONAL INFORMATION, THE CONSULTATION WITH THE TREATING	Monica Feeley (b) (4) (b) (4)	16 Sep 2020 21:11:50

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
RHEUMATOLOGIST, AND THE TIMING OF THE DEVELOPMENT OF THESE SYMPTOMS IT IS POSSIBLE THAT THE VACCINE MAY HAVE CONTRIBUTED TO THE SYMPTOMS. THUS, WE ARE CHANGING OUR ASSESSMENT THAT THERE MAY BE A POSSIBLE RELATIONSHIP BETWEEN THE SYMPTOMATOLOGY OF PT AND THE STUDY PRODUCT. AS OF TODAY HE FEELS GOOD DURING THE DAY, BUT WAKES UP IN MORNING WITH SOME PAIN IN THE SHOULDERS AND NECK. THE PAIN GOES AWAY APPROXIMATELY 2 HOURS AFTER TAKING THE 20 MG DOSE OF PREDNISONE. HE REMAINS IN CLOSE CONTACT WITH HIS RHEUMATOLOGIST. WE CONTINUE TO FOLLOW PT CLOSELY.'		
reason for change: New Information Query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted, when available.' answered with 'provided on epip' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	16 Sep 2020 21:03:52
User closed query 'Per ETRTR: Please add any treatment medications or procedures to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication), thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:30:34
User closed query 'Per ETRTR: Within Narrative, state date of admission in format "dd-mmm-yy", thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:30:24
User opened query 'PV Query: Please confirm if a COVID test was performed at the hospital and provide results, if applicable. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 19:58:43
	(b) (4), (b) (6)	04 Sep 2020 15:21:32
User opened query 'PV Query: Please provide further details of the clinical course to resolution.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 14:22:13
User opened query 'PV Query. Please provide date, units and reference ranges for the reported laboratory testing of CRP and ESR if available. If unavailable, please state as such.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 14:22:02

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted, when available.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 14:20:54
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications (i.e., prednisone) to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 13:41:16
User closed query 'PV Query: Please assess if back pain and myalgia met AE/SAE reporting criteria. If yes, please report them accordingly.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 13:36:37
User closed query 'PV query: Please report if there were any risk factors or triggers that may have caused, or worsened preexisting, back pain.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 13:36:25
User closed query 'PV query: Please provide additional information about the quality of the weakness (ie. generalized, localized to specific area, objective finding on exam, subjective symptom, associated with sensory changes, etc.).' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 13:35:37
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 13:35:33
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications (i.e., prednisone) to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'treatment indicated in narrative' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 21:46:06

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV query: Please provide additional information about the quality of the weakness (ie. generalized, localized to specific area, objective finding on exam, subjective symptom, associated with sensory changes, etc.).' answered with 'added additional information about the quality of the weakness' (Site from Safety).	Monica Feeley (b) (4)	26 Aug 2020 21:45:47
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'relevant laboratory results added to discussion' (Site from Safety).	Monica Feeley (b) (4)	26 Aug 2020 21:45:33
Query 'Per ETRTR: Please add any treatment medications or procedures to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication), thanks.' answered with 'treated added in discussion. added to con meds.' (Site from CRA).	Monica Feeley (b) (4)	26 Aug 2020 21:45:02

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
User entered '24AUG20, we received the consultation note of the rheumatology attending who saw pt 21AUG20 at Faulkner Hospital. We spoke with the rheumatologist to discuss the case in detail. At the time of enrollment pt felt well. However, pt noted that he may have started to have back pain a few days before receiving the IP. The symptoms at that time were mild and thought to be related to his chronic back pain. He received the IP on 5AUG20 and reported increased back pain over the next days and he progressively developed migratory myalgias (back, shoulders, occiput, paraspinal muscles) and weakness. He denied any local injection site reaction after vaccination. The myalgias became severe on 20AUG20, and he was not able to get of out bed because of generalized weakness. He was hospitalized between 20AUG20 and 21AUG20. Work-up was notable for CRP at 96.9 and ESR at 56. He received 15 mg of prednisone on 20AUG20. He felt much better on 21AUG20 and was discharged with a prescription of prednisone 20 mg daily, with a planned tapering over 16 days. At this time the rheumatologist thinks that PMR may be a possible diagnosis. Back pain was present before the IP administration, but the polymyalgia and the weakness developed after the vaccine administration. We are updating this adverse event to include these additional symptoms. Given this additional information, the consultation with the treating rheumatologist, and the timing of the development of these symptoms it is possible that the vaccine may have contributed to the symptoms. Thus, we are changing our assessment that there may be a possible relationship between the symptomatology of pt and the study product. As of today's conversation with pt, he feels good during the day, but wakes up in the morning with some pain in the shoulders and neck. The pain goes away approximately 2 hours after taking the 20 mg dose of prednisone. He remains in close contact with his rheumatologist. We continue to follow pt closely.' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 21:44:45

v6.020 DTW (1102)

1725 of 2162

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV query: Please report if there were any risk factors or triggers that may have caused, or worsened preexisting, back pain.' answered with 'there are no risk factors or triggers that may have caused or worsened preexisting' (Site from Safety).	Monica Feeley (b) (4)	25 Aug 2020 21:37:44
Query 'Per ETRTR: Within Narrative, state date of admission in format "dd-mmm-yy", thanks.' answered with 'updated to include date' (Site from CRA).	Monica Feeley (b) (4)	25 Aug 2020 21:29:32
User entered 'ADMITEED TO FAULKNER HOSPITAL TODAY 20AUG2020 FOR IMPORTANT WEAKNESS WITH BACK PAIN (BOTH CERVICAL AND LOW BACK PAIN) WITH ASSOCIATED MYALGIA (PARASPINAL, BILATERAL DELTOID). WORKING IS ONGOING. INCLUDES A NEGATIVE COVID SWAB. 21AUG2020- WAS DISCHARGED TODAY WITH LOW DOSE PREDNISONE. FEELS WAY BETTER.' reason for change: New Information	Monica Feeley (b) (4)	25 Aug 2020 21:29:16
Query 'PV Query: Please assess if back pain and myalgia met AE/SAE reporting criteria. If yes, please report them accordingly.' answered with 'This met SAE reporting criteria as participant was hospitalized, thus we submitted this SAE form' (Site from Safety).	Monica Feeley (b) (4)	25 Aug 2020 21:24:07
User opened query 'PV Query: Please assess if back pain and myalgia met AE/SAE reporting criteria. If yes, please report them accordingly.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:23:15
Query 'PV Query: Please assess if back and myalgia met AE/SAE reporting criteria. If yes, please report them accordingly.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:22:39
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications (i.e., prednisone) to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:22:04

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please report if there were any risk factors or triggers that may have caused, or worsened preexisting, back pain.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:19:58
User opened query 'PV query: Please provide additional information about the quality of the weakness (ie. generalized, localized to specific area, objective finding on exam, subjective symptom, associated with sensory changes, etc.).' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:19:32
User opened query 'PV Query: Please assess if back and myalgia met AE/SAE reporting criteria. If yes, please report them accordingly.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:18:54
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 20:18:07
User opened query 'Per ETRTR: Please add any treatment medications or procedures to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication), thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Aug 2020 15:46:25
User opened query 'Per ETRTR: Within Narrative, state date of admission in format "dd-mmm-yy", thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Aug 2020 15:45:17
User entered 'ADMITEED TO FAULKNER HOSPITAL TODAY FOR IMPORTANT WEAKNESS WITH BACK PAIN (BOTH CERVICAL AND LOW BACK PAIN) WITH ASSOCIATED MYALGIA (PARASPINAL, BILATERAL DELTOID). WORKING IS ONGOING. INCLUDES A NEGATIVE COVID SWAB. 21AUG2020- was discharged today with low dose prednisone. feels way better.' reason for change: New Information	Monica Feeley (b) (4)	21 Aug 2020 22:24:07
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Aug 2020 23:39:54
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	20 Aug 2020 23:39:54

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Admitted to Faulkner Hospital today for important weakness with back pain (both cervical and low back pain) with associated myalgia (paraspinal, bilateral deltoid). Working is ongoing. Includes a negative COVID swab.' reason for change: Per Query Resolution	Monica Feeley (b) (4)	20 Aug 2020 23:39:54
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Aug 2020 21:40:52
User entered empty.	Xhoi Mitre (b) (4)	20 Aug 2020 21:40:52

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '1'	System	21 Aug 2020 02:15:14
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:15:11

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '1'	System	21 Aug 2020 02:15:14
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:15:11

US3432023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '0'	System	21 Aug 2020 02:15:14
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:15:11

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:25:41

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:29:41
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:03:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 12:20:11
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 12:20:11
Data point term sent to Coder	System	05 Aug 2020 23:05:28
User entered 'Aspirin'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Stroke'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '325'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:10:55
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'per protocol okay' (Site from System).	Monica Feeley (b) (4)	05 Aug 2020 23:12:07
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 23:04:47
User entered 'UN UNK 2011'	Monica Feeley (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 23:04:47

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

[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: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:44
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:25 26 Oct 2020 17:21:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:08:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:08:05
Data point term sent to Coder User entered 'Plavix'	System Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:29 05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Stroke'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '75'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:10:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'per protocol okay' (Site from System).	Monica Feeley (b) (4)	05 Aug 2020 23:11:29
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 23:06:04
User entered 'UN UNK 2011'	Monica Feeley (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 23:06:04

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:35
Data point term sent to Coder DataPoint Verified.	System	26 Oct 2020 17:21:29
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 23:08:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 23:08:06
Data point term sent to Coder	System	05 Aug 2020 23:07:30
User entered 'Bupropion'	Monica Feeley (b) (4)	05 Aug 2020 23:06:44
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Depression'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '150'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'twice daily (BID)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:11:03
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'per protocol okay' (Site from System).	Monica Feeley (b) (4)	05 Aug 2020 23:11:35
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 23:06:44
User entered 'un UNK 1980'	Monica Feeley (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 23:06:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:45
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:45
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:23 26 Oct 2020 17:21:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 15:58:11
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 15:58:11
Data point term sent to Coder User entered 'Multivitimin'	System Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:30 05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'General Health'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '1'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'tablet (TABLET)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:11:07
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'per protocol okay' (Site from System).	Monica Feeley (b) (4)	05 Aug 2020 23:11:39
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 23:07:12
User entered 'Un UNK 2015'	Monica Feeley (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 23:07:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:42
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:25 26 Oct 2020 17:21:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 23:10:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 23:10:01
Data point term sent to Coder User entered 'Vitamin D'	System Monica Feeley (b) (4)	05 Aug 2020 23:08:30 05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'General Health'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '2000'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'IU (IU)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:11:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'per protocol okay' (Site from System).	Monica Feeley (b) (4)	05 Aug 2020 23:11:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 23:07:45
User entered 'UN UNK 2015'	Monica Feeley (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 23:07:45

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:34
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:23 26 Oct 2020 17:21:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:10:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:10:01
Data point term sent to Coder User entered 'Calcium'	System Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:08:31 05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'General Health'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '1000'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:11:15
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'per protocol okay' (Site from System).	Monica Feeley (b) (4)	05 Aug 2020 23:11:49
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 23:08:12
User entered 'Un UNK 2015'	Monica Feeley (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 23:08:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

[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: BISOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:15:46
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:15:46
Data point term sent to Coder	System	10 Nov 2020 21:28:52
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 21:28:33
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: BISOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:25
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:25
Data point term sent to Coder	System	26 Oct 2020 17:21:31
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	26 Oct 2020 17:21:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: BISOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:37:02
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:37:02
Data point term sent to Coder	System	05 Aug 2020 23:09:31
User entered 'bisoprolol'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Monica Feeley (b) (4)	10 Nov 2020 21:28:33
User entered 'HEART FAILURE/HTN' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Monica Feeley (b) (4)	10 Nov 2020 21:28:33
	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Heart failure'	Monica Feeley (b) (4)	05 Aug 2020 23:09:13
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '2.5'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN JUN 2019). Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:25:06
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN JUN 2019). Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'date correct . This is also taken for hypertension which started in 2010' (Site from DM). DataPoint Verified.	Monica Feeley (b) (4)	10 Nov 2020 21:28:20
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN JUN 2019). Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Per CDM, the Concomitant Medication end date should be less than or equal to 28 days prior to IP injection in order to be recorded in Prior/Concomitant Medication page. Please confirm the Concomitant Medication end date is less than or equal to 28 days from IP injection. Otherwise explain. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:59:04
Query 'Per CDM, the Concomitant Medication end date should be less than or equal to 28 days prior to IP injection in order to be recorded in Prior/Concomitant Medication page. Please confirm the Concomitant Medication end date is less than or equal to 28 days from IP injection. Otherwise explain. Thank you.' answered with 'per protocol required' (Site from DM).	Xhoi Mitre (b) (4)	13 Aug 2020 11:51:13
User opened query 'Per CDM, the Concomitant Medication end date should be less than or equal to 28 days prior to IP injection in order to be recorded in Prior/Concomitant Medication page. Please confirm the Concomitant Medication end date is less than or equal to 28 days from IP injection. Otherwise explain. Thank you.' (Site from DM).	(b) (4)	11 Aug 2020 17:30:18
User opened query 'Per CDM, the Concomitant Medication end date should be less than or equal to 28 days prior to IP injection in order to be recorded in Prior/Concomitant Medication page. Please confirm the Concomitant Medication end date is less than or equal to 28 days from IP injection. Otherwise explain. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Aug 2020 10:46:51

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 10:45:35
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Monica Feeley (b) (4)	05 Aug 2020 23:11:53
answered with 'per protocol okay' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 23:09:13
User entered 'UN UNK 2016'	Monica Feeley (b) (4)	05 Aug 2020 23:09:13
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'UN Jul 2020'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 23:09:13

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

[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) (b) (4)	26 Oct 2020 18:05:39
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:39
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:30 26 Oct 2020 17:21:22
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) (b) (4)	06 Aug 2020 00:56:02
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 00:56:02
Data point term sent to Coder	System	05 Aug 2020 23:10:32
User entered 'Levothyronine'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'hypothyroidism'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR-RQ: Please review the dose and unit recorded as this is not the standard dosage for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:28:43
Query 'Per DM CLR-RQ: Please review the dose and unit recorded as this is not the standard dosage for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'this is what the participant reported' (Site from DM).	Monica Feeley (b) (4)	10 Nov 2020 21:22:50
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)	04 Nov 2020 11:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User opened query 'Per DM CLR-RQ: Please review the dose and unit recorded as this is not the standard dosage for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 09:01:02
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 'Dose provided by participant' (Site from DM).	Megan Powell (b) (4)	21 Oct 2020 22:46:52
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)	01 Oct 2020 03:47:39
User entered '1.2'	Monica Feeley (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'ug (ug)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:11:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'per protocol okay' (Site from System).	Monica Feeley (b) (4)	05 Aug 2020 23:11:13
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 23:10:28
User entered 'Un UNK 2005'	Monica Feeley (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 23:10:28

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 01:49:15
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 01:49:15
Data point term sent to Coder	System	23 Nov 2020 15:26:14
Coding entries removed.	(b) (4), (b) (6)	23 Nov 2020 15:25:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:23
Data point term sent to Coder	System	26 Oct 2020 17:21:30
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:31:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:31:13
Data point term sent to Coder	System	11 Aug 2020 17:30:17
User entered 'Aspirin'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 17:29:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 17:29:42
User entered 'No (N)' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:42
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 17:29:25
User entered empty.	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

[Indication](#)

Audit	User	Time (GMT)
Query 'Per CDM re-query: Thank you for the confirmation. Please update the indication so that there will be an exact match in CM and MH form. Thank you. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:25:39
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 15:25:29
User entered 'CHRONIC LOW BACK PAIN WITH INTERMITTENT FLARE' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 15:25:29
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:28:04
User opened query 'Per CDM re-query: Thank you for the confirmation. Please update the indication so that there will be an exact match in CM and MH form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:28:02
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'please read "chronic low back pain"' (Site from DM).	Monica Feeley (b) (4)	10 Nov 2020 21:22:06
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:58:20
User entered 'Back pain'	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '325'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'as needed (PRN)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:11:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'per protocol required' (Site from System).	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:55
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 17:29:25
User entered 'UN UNK 2000'	Xhoi Mitre (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:29:25

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids $\geq$ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:05:12
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:47
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	(b) (4)	26 Oct 2020 18:05:47
Data point term sent to Coder DataPoint Verified.	System	26 Oct 2020 17:21:30
	(b) (4), (b) (6)	26 Oct 2020 17:21:22
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids $\geq$ 20 mg/day of prednisone equivalent).' answered with 'per clinician, participant met eligibility criteria. Medication and diagnosis began after visit 1 ' (Site from DM).	Megan Powell (b) (4)	21 Oct 2020 22:52:19
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids $\geq$ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:52:07
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Sep 2020 08:29:44

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'prednisone'	Coder Import (b) (4) (b) (4) System Monica Feeley (b) (4) (b) (4)	01 Sep 2020 08:29:44 31 Aug 2020 20:48:44 31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'possible polymyalgia rheumatica'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '20'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '21 Aug 2020'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)' reason for change: New Information	Phoebe Cunningham (b) (4)	12 Sep 2020 12:50:49
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	12 Sep 2020 15:27:02
User entered '04 Sep 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	12 Sep 2020 15:27:02
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	12 Sep 2020 12:50:49
User entered 'un UNK 2020' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	12 Sep 2020 12:50:49
User entered empty.	Monica Feeley (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 20:47:55

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:48
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:48
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:31 26 Oct 2020 17:21:22
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:29:46
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 Sep 2020 08:29:46
Data point term sent to Coder	System	31 Aug 2020 20:49:45
User entered 'prednisone'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'possible polymyalgia rheumatica'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '15'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once (ONCE)'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '20 Aug 2020'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '20 Aug 2020'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 20:48:52

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:12:30
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' answered with 'does not' (Site from DM).	Monica Feeley (b) (4)	10 Nov 2020 21:29:17
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Oct 2020 18:05:29
Data point term sent to Coder	System	26 Oct 2020 17:21:32
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:52:38
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Sep 2020 12:53:46

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	12 Sep 2020 12:53:46
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	12 Sep 2020 12:53:06
User entered 'Prednisone'	Phoebe Cunningham	12 Sep 2020 12:52:08
	(b) (4)	

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'POLYMYALGIA RHEUMATICA'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '20'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '11 Sep 2020'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 12:52:08

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:31
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:32 26 Oct 2020 17:21:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 19:28:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 19:28:41
Data point term sent to Coder User entered 'Rosuvastatin'	System Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:27:51 12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Hyperlipidemia'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '40'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'UN UNK 2018'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 19:27:43

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

[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: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:36
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:36
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:33 26 Oct 2020 17:21:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 00:44:36
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 00:44:36
Data point term sent to Coder User entered 'Atenolol'	System Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:36:57 12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Premature ventricular complex'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '25'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once daily (QD)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'UN UNK 2010'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 19:36:12

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:37
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:37
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:31 26 Oct 2020 17:21:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 20:41:40
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 20:41:40
Data point term sent to Coder User entered 'Colase'	System Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:58 12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Constipation'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'UNK'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Other (OTHER)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'UNK'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'as needed (PRN)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'UN Jan 2020'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:37:02

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:41
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:34 26 Oct 2020 17:21:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 19:38:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 19:38:35
Data point term sent to Coder User entered 'Flonase'	System Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:58 12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:22:18
Query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'added' (Site from DM).	Monica Feeley (b) (4)	10 Nov 2020 21:27:01
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User opened query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 04:32:11
User entered 'seasonal allergies'	Monica Feeley (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '2'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'puff (PUFF)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'as needed (PRN)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Nasal (NASAL)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'UN UNK 2010'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:37:40

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:28
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	26 Oct 2020 17:21:34 26 Oct 2020 17:21:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:30:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:30:52
Data point term sent to Coder User entered 'Flu vaccine'	System Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:30:21 01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'prophylaxis for influenza'	Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '1'	Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Other (OTHER)'	Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'injection'	Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'once (ONCE)'	Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'Intramuscular (INTRAMUSCULAR)'	Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered empty.	Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '25 Sep 2020'	Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '0'	Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered '25 Sep 2020'	Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:21:22
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 20:30:09

US3432023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 20:30:09

US3432023

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:25:41

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 22:15:03

US3432023

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:25:41

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'SAE (specify) (SAE)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 22:15:03

US3432023

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:25:41

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User closed query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 18:12:38
Query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' answered with 'Updated' (Site from DM).	Alexander Mills (b) (4)	24 Nov 2020 14:36:48
User entered 'SAE #1' reason for change: Per Query Resolution	Alexander Mills (b) (4)	24 Nov 2020 14:36:42
User opened query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:08:04
User entered 'Possible Polymyalgia Rheumatica'	Monica Feeley (b) (4)	14 Oct 2020 22:15:03

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'USA-US078-2020-MRNA-1273-P301000001'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:18
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:40
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:35
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:48
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Lindsey'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Baden'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'MA'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:46:44
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'US' (non-conformant).	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Oct 2020 20:16:53
User entered '6'	System	15 Oct 2020 13:43:02
User entered '5'	System	17 Sep 2020 12:34:26
User entered '4'	System	27 Aug 2020 13:43:11
User entered '3'	System	26 Aug 2020 14:11:26
User entered '2'	System	24 Aug 2020 15:19:21
User entered '1'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'USA-US078-2020-MRNA-1273-P301000001'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:18
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:40
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:35
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:48
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Lindsey'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Baden'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'MA'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:46:44
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'US' (non-conformant).	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Oct 2020 20:16:53
User entered '6'	System	15 Oct 2020 13:43:02
User entered '5'	System	17 Sep 2020 12:34:26
User entered '4'	System	27 Aug 2020 13:43:11
User entered '3'	System	26 Aug 2020 14:11:26
User entered '2'	System	24 Aug 2020 15:19:21
User entered '1'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:25:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:02
User entered '21/Aug/2020 09:37'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:25:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:05
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered '1'	(b) (4), (b) (6)	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'USA-US078-2020-MRNA-1273-P301000001'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:18
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:40
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:35
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:48
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Lindsey'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Baden'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'MA'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:46:44
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'US' (non-conformant).	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Oct 2020 20:16:53
User entered '6'	System	15 Oct 2020 13:43:02
User entered '5'	System	17 Sep 2020 12:34:26
User entered '4'	System	27 Aug 2020 13:43:11
User entered '3'	System	26 Aug 2020 14:11:26
User entered '2'	System	24 Aug 2020 15:19:21
User entered '1'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:25:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:17
User entered '24/Aug/2020 11:19'	System	24 Aug 2020 15:19:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:25:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:24
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered '1'	(b) (4), (b) (6)	24 Aug 2020 15:19:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'USA-US078-2020-MRNA-1273-P301000001'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:18
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:40
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:35
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:48
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Lindsey'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Baden'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'MA'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:46:44
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'US' (non-conformant).	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Oct 2020 20:16:53
User entered '6'	System	15 Oct 2020 13:43:02
User entered '5'	System	17 Sep 2020 12:34:26
User entered '4'	System	27 Aug 2020 13:43:11
User entered '3'	System	26 Aug 2020 14:11:26
User entered '2'	System	24 Aug 2020 15:19:21
User entered '1'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:25:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:29
User entered '26/Aug/2020 10:11'	System	26 Aug 2020 14:11:26

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:25:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:30
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 13:42:55
User entered '1'	(b) (4), (b) (6)	26 Aug 2020 14:11:26

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'USA-US078-2020-MRNA-1273-P301000001'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:18
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:40
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:35
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:48
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Lindsey'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Baden'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'MA'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:46:44
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'US' (non-conformant).	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Oct 2020 20:16:53
User entered '6'	System	15 Oct 2020 13:43:02
User entered '5'	System	17 Sep 2020 12:34:26
User entered '4'	System	27 Aug 2020 13:43:11
User entered '3'	System	26 Aug 2020 14:11:26
User entered '2'	System	24 Aug 2020 15:19:21
User entered '1'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:25:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:36
User entered '27/Aug/2020 09:43'	System	27 Aug 2020 13:43:11

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:25:41

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)	17 Sep 2020 12:34:12
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:19:38
User entered '1'	(b) (4), (b) (6)	27 Aug 2020 13:43:11

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'USA-US078-2020-MRNA-1273-P301000001'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:18
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:40
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:35
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:48
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Lindsey'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Baden'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'MA'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:46:44
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'US' (non-conformant).	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Oct 2020 20:16:53
User entered '6'	System	15 Oct 2020 13:43:02
User entered '5'	System	17 Sep 2020 12:34:26
User entered '4'	System	27 Aug 2020 13:43:11
User entered '3'	System	26 Aug 2020 14:11:26
User entered '2'	System	24 Aug 2020 15:19:21
User entered '1'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:25:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:30:10
User entered '17/Sep/2020 08:34'	System	17 Sep 2020 12:34:26

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:25:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:30:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:42:52
User entered '1'	(b) (4), (b) (6)	17 Sep 2020 12:34:26

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'USA-US078-2020-MRNA-1273-P301000001'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:18
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:40
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:35
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:48
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Lindsey'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Baden'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'MA'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:46:44
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'US' (non-conformant).	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Oct 2020 20:16:53
User entered '6'	System	15 Oct 2020 13:43:02
User entered '5'	System	17 Sep 2020 12:34:26
User entered '4'	System	27 Aug 2020 13:43:11
User entered '3'	System	26 Aug 2020 14:11:26
User entered '2'	System	24 Aug 2020 15:19:21
User entered '1'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:25:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:30:10
User entered '15/Oct/2020 09:43'	System	15 Oct 2020 13:43:02

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:25:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:30:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 20:16:36
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 13:43:02

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'USA-US078-2020-MRNA-1273-P301000001'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:18
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:40
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'Yes (Y)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:35
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:48
Reviewed for Safety.	(b) (4), (b) (6)	21 Aug 2020 13:37:12
User entered 'No (N)'	System	21 Aug 2020 13:36:22

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Lindsey'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'Baden'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:08:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:34:12
Amendment Manager: User entered 'MA'	System	14 Sep 2020 21:44:13

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:46:44
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:18:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:11:08
User entered 'US' (non-conformant).	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Oct 2020 20:16:53
User entered '6'	System	15 Oct 2020 13:43:02
User entered '5'	System	17 Sep 2020 12:34:26
User entered '4'	System	27 Aug 2020 13:43:11
User entered '3'	System	26 Aug 2020 14:11:26
User entered '2'	System	24 Aug 2020 15:19:21
User entered '1'	System	21 Aug 2020 13:37:21

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 09:25:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:30:10
User entered '22/Oct/2020 20:16'	System	22 Oct 2020 20:16:53

US3432023

Folder: SAE USA-US078-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 09:25:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:30:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 20:17:37
User entered '1'	(b) (4), (b) (6)	22 Oct 2020 20:16:53