

US3602030 (Prod: Hackensack University Medical Center)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:08:32

All time stamps listed in this document are displayed in GMT

US3602030

Form: Participant Creation

Generated On: 26 Nov 2020 11:08:32

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:32

Date of Birth (MMM yyyy)	(b) (6) 1979
Age	41
Age Units	YEARS
Age (Derived)	41
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
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	True
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:32

Date of Informed Consent (<i>dd MMM yyyy</i>)	11 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:08:32

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:08:32

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:32

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:32

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:32

Condition	DRY EYE SYNDROME
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)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:32

Condition	ACID REFLUX
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)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:32

Condition	HAIR THINNING
Start date (dd MMM yyyy)	11 AUG 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)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:32

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

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:32

Condition	INSOMNIA
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)	_____

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:32

Condition	VITAMIN D INSUFFICIENCY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:32

Condition	LEFT KNEE OSTEOARTHRITIS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:32

Condition	NON-ALLERGIC RHINITIS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:08:32

Condition	ENDOMETRIOSIS S/P STRIPPING
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:08:32

Condition	TOOTH CLEANING
Start date (dd MMM yyyy)	6 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	6 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:08:32

Condition	ROOT CANAL
Start date (dd MMM yyyy)	28 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	28 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:08:32

Condition	MULTIPLE SINUS SURGERIES
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐
	No ☒
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:12 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 09:12
Height (<i>xxx.x</i>)	63 in
Weight (<i>xxx.x</i>)	218 lb
BMI (<i>xxx.x</i>)	38.69771 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:32

Date of assessment (*dd MMM yyyy*) 11 SEP 2020

Is the participant of childbearing potential? Yes ☒ No ☐

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	11 SEP 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

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

ADMIN, NOT EXPOSED TO PEOPLE, REMOTE

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) True

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Folder: Screening

Form: Risk of Exposure

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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)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:32

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

What was the participant's randomization number? 113375

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:32

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

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)	11 SEP 2020
Time of assessment (00:00-23:59)	09:12 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 09:12
Temperature (xxx.x)	96.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

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)	11 SEP 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:00
Temperature (xxx.x)	98.6 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:32

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed _____ Urine ☐

Serum ☐

Result _____ Positive ☐

Negative ☐

Was FSH sample collected? Yes ☐

No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to ☐
	Adverse Event ☐
	Physician withheld dose due to ☐
	Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by ☐
	Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	11 SEP 2020
What was the treatment time? (00:00-23:59)	11:30 (24 HR)
Treatment Date and Time (derived)	11 SEP 2020 11:30
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:32

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	11 SEP 2020
Collection time (<i>00:00-23:59</i>)	09:12 (24 HR)
Collection date and time (derived)	11 SEP 2020 09:12

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:08:32

Collection date (<i>dd MMM yyyy</i>)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:12	11 SEP 2020 09:12
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 12:02

PC Open Date & Time

11 SEP 2020 11:50

PC Close Date & Time

11 SEP 2020 14:20

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp 11 SEP 2020 19:21

PC Open Date & Time 11 SEP 2020 15:15

PC Close Date & Time 12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 14:10

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 13:21

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:32

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 12:41

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 13:21

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

16 SEP 2020 12:15

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

17 SEP 2020 12:24

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 12:03

PC Open Date & Time

11 SEP 2020 11:50

PC Close Date & Time

11 SEP 2020 14:20

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 19:21

PC Open Date & Time

11 SEP 2020 15:15

PC Close Date & Time

12 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 14:09

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:32

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

13 SEP 2020 13:21

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 12:41

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 13:20

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 12:16

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 12:24

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 12:03
PC Open Date & Time	11 SEP 2020 11:50
PC Close Date & Time	11 SEP 2020 14:20

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 19:22
PC Open Date & Time	11 SEP 2020 15:15
PC Close Date & Time	12 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

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 ☒

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

Yes ☐	
PC Time stamp	12 SEP 2020 14:10
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

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 ☒

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

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 ☒

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

Yes ☐	
PC Time stamp	14 SEP 2020 12:42
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

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 ☒

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

Yes ☐	
PC Time stamp	15 SEP 2020 13:19
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

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 ☒

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

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 ☒

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 08:55
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	FOREHEAD
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 11:05
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3602030

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

US3602030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	16 OCT 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

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)	16 OCT 2020
What was the treatment time? (00:00-23:59)	10:36 (24 HR)
Treatment Date and Time (derived)	16 OCT 2020 10:36
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

US3602030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:32

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

16 OCT 2020

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

09:06 (24 HR)

Collection date and time (derived)

16 OCT 2020 09:06

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:08:32

Collection date (dd MMM yyyy)			16 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:06	16 OCT 2020 09:06
Nasopharyngeal Swab 2	No		

US3602030

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

16 OCT 2020 11:10

PC Open Date & Time

16 OCT 2020 10:56

PC Close Date & Time

16 OCT 2020 13:26

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

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 98.8 °F

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

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

PC Time Stamp	16 OCT 2020 18:33
PC Open Date & Time	16 OCT 2020 14:21
PC Close Date & Time	17 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

17 OCT 2020 15:40

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:32

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

18 OCT 2020 14:14

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:32

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 15:17

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 12:09

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 14:02

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp 22 OCT 2020 14:06

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

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

16 OCT 2020 11:11

PC Open Date & Time

16 OCT 2020 10:56

PC Close Date & Time

16 OCT 2020 13:26

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

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

16 OCT 2020 18:34

PC Open Date & Time

16 OCT 2020 14:21

PC Close Date & Time

17 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:32

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

17 OCT 2020 15:41

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:32

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

18 OCT 2020 14:14

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:32

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

19 OCT 2020 15:18

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:32

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

20 OCT 2020 12:08

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:32

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

21 OCT 2020 14:02

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:32

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

22 OCT 2020 14:06

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

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

No ☒

Yes ☐

PC Time stamp	16 OCT 2020 11:11
PC Open Date & Time	16 OCT 2020 10:56
PC Close Date & Time	16 OCT 2020 13:26

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

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

No ☒

Yes ☐

PC Time stamp	16 OCT 2020 18:35
PC Open Date & Time	16 OCT 2020 14:21
PC Close Date & Time	17 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

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 ☒

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

Yes ☐	
PC Time stamp	17 OCT 2020 15:41
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

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 ☒

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

Yes ☐	
PC Time stamp	18 OCT 2020 14:15
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

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 ☒

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

Yes ☐	
PC Time stamp	19 OCT 2020 15:18
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

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 ☒

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

Yes ☐	
PC Time stamp	20 OCT 2020 12:08
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

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 ☒

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

Yes ☐	
PC Time stamp	21 OCT 2020 14:03
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

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 ☒

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

Yes ☐	
PC Time stamp	22 OCT 2020 14:06
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3602030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	13 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	09:25 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 09:25
Temperature (<i>xxx.x</i>)	97.4 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602030

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 NOV 2020

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

US3602030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:32

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	13 NOV 2020
Collection time (<i>00:00-23:59</i>)	09:25 (24 HR)
Collection date and time (derived)	13 NOV 2020 09:25

US3602030

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 09:35:40

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2020 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 75

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 09:16:29

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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10 DEC 2020 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

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13 DEC 2020 00:01

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17 DEC 2020 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2020 00:01

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24 DEC 2020 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 DEC 2020 00:01

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31 DEC 2020 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2021 00:01

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07 JAN 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

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10 JAN 2021 00:01

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14 JAN 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

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11 FEB 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

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24 JUN 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

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12 AUG 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

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19 AUG 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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°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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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°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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

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06 JAN 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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13 JAN 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

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20 JAN 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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°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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

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27 JAN 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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17 FEB 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

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24 FEB 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

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03 MAR 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

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13 MAR 2022 00:01

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17 MAR 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

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24 MAR 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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31 MAR 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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03 APR 2022 00:01

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07 APR 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

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10 APR 2022 00:01

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14 APR 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

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17 APR 2022 00:01

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21 APR 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

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24 APR 2022 00:01

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28 APR 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

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05 MAY 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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12 MAY 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

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19 MAY 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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02 JUN 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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09 JUN 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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12 JUN 2022 00:01

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16 JUN 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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23 JUN 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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30 JUN 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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07 JUL 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

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10 JUL 2022 00:01

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14 JUL 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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°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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

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17 JUL 2022 00:01

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21 JUL 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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28 JUL 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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31 JUL 2022 00:01

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04 AUG 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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14 AUG 2022 00:01

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18 AUG 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

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21 AUG 2022 00:01

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25 AUG 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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28 AUG 2022 00:01

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US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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°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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3602030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3602030

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:08:32

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3602030

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:08:32

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 11:08:32

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
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)	

US3602030

Folder: Illness Visit (2)

Form: Saliva Collection

Generated On: 26 Nov 2020 11:08:32

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3602030

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	22 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	8:52 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 8:52
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	96.4 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	UNKNOWN
Pulse (<i>xxx</i>)	98 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602030

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3602030

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:08:32

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3602030

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

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 _____

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

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)	

US3602030

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:32

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.

US3602030

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:08:32

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3602030

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

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	SICKD28
------------	---------

US3602030

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

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)	

US3602030

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:32

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.

US3602030

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:08:32

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3602030

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

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 _____

US3602030

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

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)	

US3602030

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:32

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.

US3602030

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:08:32

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection _____

US3602030

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:08:32

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

AEID	USA-US079-2020-MRNA-1273-P30 1000001
Adverse event	SWELLING TO THE RIGHT SIDE OF THE FACE
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	17 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	27 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

PT HAD HER IP ON SEP 11TH

HAD HER TOOTH CLEANING
AND ROOT CANAL DONE AUG
6TH AND AUGUST 28TH AND
WAS WELL PRIOR TO THE
VACCINE
PMHX OF SINUS SURGERIES IN
THE PAST

NO ISSUES RELATED TOT HE
VACCINE ITSELF BUT THEN ON
THURSDAY STARTED WITH
PAIN ON CHEWING IN THE
BACK TEETH AND THOUGHT
WAS RELATED TO THE ROOT
CANAL AND NEVER
MENTIONED IT ON THE SAFETY
CALL WITH ME ON FRIDAY THE
18TH

OVER THE NEXT 24HR HAD
INCREASING TINGLING AND
NUMBNESS ALONG THE JAW
LINE AND INCREASING
SWELLING AND FULLNESS
OVER THE MAXILLA
NO NASAL DISCHARGE
THE PAIN PERSISTED ON THE
WEEKEND AND SHE SAW HER
DENTIST ON 9/21 AND CALLED
ME FROM THERE SINCE THE
DENTIST DID NOT FIND ANY
ISSUES WITH THE TOOTH AND
FELT THAT IT COULD BE
SHINGLES AND OF SOME
OTHER MEDICAL ISSUES
LEADING TO REFERRED PAIN

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

ON TODAY'S LIMITED EXAM:
VITALS : 96.4 , 128/81, PLSE OX
100% HR 98 RR 12
BMI 38.4
SHE DOES HAVE SWELLING TO
THE CHEEK AND JAW AREA
NO REDNESS TO THE FACE
NO TOOTH DECAY NOTED , NO
PAIN ON PALPATION OF THE
TOOTH
NO SWELLING OF THE JAW
NO FACIAL DROOP
NO NASAL CONGESTION OR
REDNESS

REC : SEEK EVAL BY ENT AND
OR MEDICAL DOCTOR
HAVE THE DENTIST AND THE
OTHER PHYSICIANS SHE SEES
TO FAX THE RECORDS TO US

(b) (6)

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

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

AEID	USA-US079-2020-MRNA-1273-P30 1000001
Adverse event	ANXIETY RELATED TO THE VACCINE
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	17 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	7 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

NO ISSUES RELATED TOT HE
VACCINE ITSELF BUT THEN ON
THURSDAY STARTED WITH
PAIN ON CHEWING IN THE
BACK TEETH AND THOUGHT
WAS RELATED TO THE ROOT
CANAL AND NEVER
MENTIONED IT ON THE SAFETY
CALL WITH ME ON FRIDAY THE
18TH
ON TODAY'S LIMITED EXAM:
VITALS : 96.4 , 128/81, PLSE OX
100% HR 98 RR 12
BMI 38.4
SHE DOES HAVE SWELLING TO
THE CHEEK AND JAW AREA
NO REDNESS TO THE FACE
NO TOOTH DECAY NOTED , NO
PAIN ON PALPATION OF THE
TOOTH
NO SWELLING OF THE JAW
NO FACIAL DROOP
NO NASAL CONGESTION OR
REDNESS

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)	

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

AEID	USA-US079-2020-MRNA-1273-P30 1000001
Adverse event	TINGLING ON RIGHT SIDE OF FACE
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	17 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	28 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

PT HAD HER IP ON SEP 11TH

HAD HER TOOTH CLEANING
AND ROOT CANAL DONE AUG
6TH AND AUGUST 28TH AND
WAS WELL PRIOR TO THE
VACCINE
PMHX OF SINUS SURGERIES IN
THE PAST

NO ISSUES RELATED TOT HE
VACCINE ITSELF BUT THEN ON
THURSDAY STARTED WITH
PAIN ON CHEWING IN THE
BACK TEETH AND THOUGHT
WAS RELATED TO THE ROOT
CANAL AND NEVER
MENTIONED IT ON THE SAFETY
CALL WITH ME ON FRIDAY THE
18TH

OVER THE NEXT 24HR HAD
INCREASING TINGLING AND
NUMBNESS ALONG THE JAW
LINE AND INCREASING
SWELLING AND FULLNESS
OVER THE MAXILLA
NO NASAL DISCHARGE
THE PAIN PERSISTED ON THE
WEEKEND AND SHE SAW HER
DENTIST ON 9/21 AND CALLED
ME FROM THERE SINCE THE
DENTIST DID NOT FIND ANY
ISSUES WITH THE TOOTH AND
FELT THAT IT COULD BE
SHINGLES AND OF SOME
OTHER MEDICAL ISSUES
LEADING TO REFERRED PAIN

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

ON TODAY'S LIMITED EXAM:
VITALS : 96.4 , 128/81, PLSE OX
100% HR 98 RR 12
BMI 38.4
SHE DOES HAVE SWELLING TO
THE CHEEK AND JAW AREA
NO REDNESS TO THE FACE
NO TOOTH DECAY NOTED , NO
PAIN ON PALPATION OF THE
TOOTH
NO SWELLING OF THE JAW
NO FACIAL DROOP
NO NASAL CONGESTION OR
REDNESS

REC : SEEK EVAL BY ENT AND
OR MEDICAL DOCTOR
HAVE THE DENTIST AND THE
OTHER PHYSICIANS SHE SEES
TO FAX THE RECORDS TO US

(b) (6)

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)	

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

AEID	USA-US079-2020-MRNA-1273-P30 1000001
Adverse event	LEFT SIDED PLEURITIC CHEST PAIN
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	27 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	29 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

L SIDED BACK / THORACIC
CHEST PAIN SO SHE WENT TO
HER PCP ON 9/28 AND HAD AN
EKG DONE WHICH WAS
NORMAL . SHE HAD LABS
DONE TODAY (NL) AND HAD A
CXR DONE WHICH WAS ALSO
NORMAL . . NO MEDS AND NO
OTC TAKE THUS FAR . WAS
SENT TO THE CARDIOLOGIST
(b) (6) , WHOM SHE SAW
TODAY 10/7 AND HAD
EVALUATION DONE . HE DID
NOT THINK IT IS CARDIAC IN
ORIGIN BUT REC ECHO (10/9)
AND STRESS TEST ON (10/13)

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)	

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

AEID	USA-US079-2020-MRNA-1273-P30 1000001
Adverse event	LEFT SIDED CHEST WALL WARMTH
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)	6 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	16 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

WILL NOT BE PURSUING THE
SECOND DOSE OF THE
INVESTIGATIONAL PRODUCT
STARTED WITH CHEST WALL
PAIN AND TINGLING AND
FEELING OF WARMTH TO THE
SIDE THAT STARTED
YESTERDAY EVENING WHILE
LYING DOWN AND
MENTIONED IT TO THE
CARDIOLOGIST TOO . SHE HAS
BEEN RECOMMENDED TO
HAVE THE NEUROLOGIST
ASSESS HER FOR ANY
ETIOLOGY FOR THE
SYMPTOMS
PT IS GOING TO BE MAKING AN
APPT AND WILL LET US KNOW
THE OUTCOME

SHE DOES ASK ME TO UN
BLIND HER FROM THE STUDY
GIVEN VARIOUS SYMPTOMS
WITH NO DIAGNOSIS MADE
AND CONCERN FOR VACCINE
RELATED ISSUES

I HAVE HAD THE DISCUSSION
WITH (b) (6) REG THE
SAME

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)	
--	--

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

AEID	USA-US079-2020-MRNA-1273-P30 1000001
Adverse event	LEFT SIDED TINGLING
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)	6 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	16 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	380 of 2421

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

STARTED WITH CHEST WALL
PAIN AND TINGLING AND
FEELING OF WARMTH TO THE
SIDE THAT STARTED
YESTERDAY EVENING WHILE
LYING DOWN AND
MENTIONED IT TO THE
CARDIOLOGIST TOO . SHE HAS
BEEN RECOMMENDED TO
HAVE THE NEUROLOGIST
ASSESS HER FOR ANY
ETIOLOGY FOR THE
SYMPTOMS
PT IS GOING TO BE MAKING AN
APPT AND WILL LET US KNOW
THE OUTCOME

SHE DOES ASK ME TO UN
BLIND HER FROM THE STUDY
GIVEN VARIOUS SYMPTOMS
WITH NO DIAGNOSIS MADE
AND CONCERN FOR VACCINE
RELATED ISSUES

I HAVE HAD THE DISCUSSION
WITH (b) (6) REG THE
SAME

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)	

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

AEID	
Adverse event	HEADACHE
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)	18 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	24 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

AEID	
Adverse event	MIGRAINE HEADACHE
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)	04 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	04 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

AEID	
Adverse event	MIGRAINE HEADACHE
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)	02 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	03 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:08:32

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

Yes ☒

No ☐

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

Name of Medication	NEXPLANON
Prophylaxis	Yes ☐ No ☒
Indication	CONTRACEPTION AND ENDOMETRIOSIS
Dose per administration	N/A
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	N/A
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	Q 3YEARS
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	INTRADERMAL	
Start date (dd MMM yyyy)	24 JUN 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	☐

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

Name of Medication	ADVAIR
Prophylaxis	Yes ☒ No ☐
Indication	ASTHMA
Dose per administration	250/50
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MCG
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 ☐

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

	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 2004	
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 ☒	

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

Name of Medication	TELMISARTAN
Prophylaxis	Yes ☐ No ☒
Indication	HTN
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 ☐

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

	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 2012
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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

Name of Medication	RESTASIS 0.5 MG/ML
Prophylaxis	Yes ☐ No ☒
Indication	DRY EYE
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	GTTS
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

Name of Medication	ASTELIN 0.15%
Prophylaxis	Yes ☒ No ☐
Indication	NON- ALLERGIC RHINITIS
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

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
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Start date completely unknown	False
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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
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Interval Dosage Unit Number (derived)	1
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Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

Name of Medication	NEXIUM
Prophylaxis	Yes ☒ No ☐
Indication	ACID REFLUX
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 ☐

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

Name of Medication	FLONASE 50MCG
Prophylaxis	Yes ☒ No ☐
Indication	NON- ALLERGIC RHINITIS
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 ☐

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

Name of Medication	MELATONIN
Prophylaxis	Yes ☒ No ☐
Indication	INSOMNIA
Dose per administration	3
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	2X A WEEK Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ☒ No ☐
Indication	GOOD 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 ☐

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

Name of Medication	BIOTIN
Prophylaxis	Yes ☒ No ☐
Indication	THINNING OF HAIR
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 ☐

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

Name of Medication	PROBIOTIC
Prophylaxis	Yes ☒ No ☐
Indication	GOOD GI 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 ☐

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

	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)		18 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		18 OCT 2020
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

Name of Medication	EXCEDRIN MIGRAINE
Prophylaxis	Yes ☐ No ☒
Indication	HEADACHE
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 ☐

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

	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)		23 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:08:32

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:08:32

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
21 SEP 2020	DENTIST VISIT	Adverse Event	
07 OCT 2020	EKG	Adverse Event	
07 OCT 2020	STRESS TEST	Adverse Event	
28 SEP 2020	CT SCAN	Adverse Event	

US3602030

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:08:32

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3602030

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:08:32

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 ☐

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

SAEID	USA-US079-2020-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	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:08:32

SAEID	USA-US079-2020-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	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	23/SEP/2020 07:39
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

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:08:32

SAEID	USA-US079-2020-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	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	08/OCT/2020 12:50
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

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:08:32

SAEID	USA-US079-2020-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	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	12/OCT/2020 12:31
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

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:08:32

SAEID	USA-US079-2020-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	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	28/OCT/2020 15:33
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

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:08:32

SAEID	USA-US079-2020-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	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	29/OCT/2020 09:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 11:08:32

SAEID	USA-US079-2020-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	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	30/OCT/2020 08:37
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

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 11:08:32

SAEID	USA-US079-2020-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	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	10/NOV/2020 15:36
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

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 11:08:32

SAEID	USA-US079-2020-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	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	19/NOV/2020 19:47
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

US3602030 (Prod: Hackensack University Medical Center)

US3602030

Form: Participant Creation

Generated On: 26 Nov 2020 11:08:32

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3602030'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Sep 2020 13:44:25

US3602030

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 14:26:17

US3602030

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Sep 2020 13:44:26

US3602030

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Sep 2020 14:26:17

US3602030

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	11 Sep 2020 14:26:17

US3602030

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:32

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1979'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Sep 2020 13:44:27

US3602030

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:32

[Age](#)

Audit	User	Time (GMT)
User entered '41'	(b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:32

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:32

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '41'	System	11 Sep 2020 14:26:54

US3602030

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:32

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:32

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:32

White

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:32

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:32

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:32

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:32

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:32

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:32

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:32

Unknown

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:32

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 14:26:54

US3602030

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	11 Sep 2020 14:26:54

US3602030

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '2020'	System	11 Sep 2020 14:26:54

US3602030

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:32

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	11 Sep 2020 14:26:54

US3602030

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 14:26:54

US3602030

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:32

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 14:26:54

US3602030

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:32

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 14:26:54

US3602030

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:32

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 14:26:54

US3602030

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:32

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Sep 2020 13:44:26

US3602030

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:32

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:27:03

US3602030

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 14:27:03

US3602030

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:08:32

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 14:31:07
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 15:57:41

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:32

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:36:35
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'not all asthma requires treatment. personally I am not being treated for asthma currently. subject may be stable at the time being and does not require baseline treatment. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 17:35:45
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 13:56:54
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 14:35:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 14:35:36
Data point term sent to Coder	System	16 Sep 2020 14:34:44
User entered 'Asthma'	(b) (4), (b) (6)	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'UN UNK 1995'	(b) (4), (b) (6)	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '1995'	System	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:32

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:35:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:35:37
Data point term sent to Coder	System	16 Sep 2020 14:34:44
User entered 'Hypertension'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'UN UNK 2014'	(b) (4), (b) (6)	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '2014'	System	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:32

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Lacrimation disorders, PT: Dry eye, LLT: Dry eye syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:35:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:35:53
Data point term sent to Coder	System	16 Sep 2020 14:34:44
User entered 'Dry Eye Syndrome'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	(b) (4), (b) (6)	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '2012'	System	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:32

[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: Gastrooesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 14:36:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 14:36:40
Data point term sent to Coder	System	16 Sep 2020 14:35:45
User entered 'Acid Reflux'	(b) (4), (b) (6)	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	(b) (4), (b) (6)	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '2010'	System	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:32

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Alopecias, PT: Alopecia, LLT: Hair thinning - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:36:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:36:40
Data point term sent to Coder	System	16 Sep 2020 14:35:47
User entered 'Hair Thinning'	(b) (4), (b) (6) (b) (4)	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '11 Aug 2020'	(b) (4), (b) (6)	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '2020'	System	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:32

[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)	16 Sep 2020 14:36:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 14:36:40
Data point term sent to Coder	System	16 Sep 2020 14:35:48
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	(b) (4), (b) (6)	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '2015'	System	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:32

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 14:37:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 14:37:08
Data point term sent to Coder	System	16 Sep 2020 14:35:47
User entered 'Insomnia'	(b) (4), (b) (6)	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	(b) (4), (b) (6)	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '2010'	System	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:32

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the diagnosis/medical condition as opposed to the LABORATORY ABNORMALITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:39:36
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:55:32
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 17:55:32
Data point term sent to Coder	System	21 Oct 2020 17:54:47
Query 'Per DM CLR: Please specify the diagnosis/medical condition as opposed to the LABORATORY ABNORMALITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 17:54:29
Coding entries removed.	(b) (4), (b) (6)	21 Oct 2020 17:54:19
User entered 'Vitamin D Insufficiency' reason for change: Per Query Resolution	(b) (4), (b) (6)	21 Oct 2020 17:54:19
User opened query 'Per DM CLR: Please specify the diagnosis/medical condition as opposed to the LABORATORY ABNORMALITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 13:57:50
User coded data point as SOC: Investigations, HLGT: Metabolic, nutritional and blood gas investigations, HLT: Vitamin analyses, PT: Vitamin D decreased, LLT: Vitamin D low - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:37:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:37:45
Data point term sent to Coder	System	16 Sep 2020 14:36:48

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:32

[Condition](#)

Audit	User	Time (GMT)
User entered 'Low Vitamin D'	(b) (4), (b) (6)	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:32

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:38:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:38:49
Data point term sent to Coder	System	16 Sep 2020 14:37:49
User entered 'Left Knee Osteoarthritis'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:32

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Rhinitis, LLT: Rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 14:38:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 14:38:47
Data point term sent to Coder	System	16 Sep 2020 14:37:52
User entered 'Non-Allergic Rhinitis'	(b) (4), (b) (6)	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:08:32

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 09:00:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 09:00:52
Data point term sent to Coder	System	16 Sep 2020 14:37:52
User entered 'Endometriosis s/p Stripping'	(b) (4), (b) (6) (b) (4)	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:08:32

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Dental cleaning, LLT: Dental cleaning - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 15:53:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 15:53:09
Data point term sent to Coder	System	15 Oct 2020 13:21:29
User entered 'Tooth Cleaning'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '6 Aug 2020'	(b) (4), (b) (6)	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '6 Aug 2020'	(b) (4), (b) (6)	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '2020'	System	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '2020'	System	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:08:32

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:23:30
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'doesnt say why subject had a root canal, simply states subject had root canal and teeth cleaning on 8/6/2020' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:35:17
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:57:30
User coded data point as SOC: Surgical and medical procedures, HLG: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Endodontic procedure, LLT: Root canal procedure - version MedDRA\23.0.	Coder Import (b) (4)	15 Oct 2020 13:22:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Oct 2020 13:22:28
Data point term sent to Coder	System	15 Oct 2020 13:21:30
User entered 'Root Canal'	(b) (4), (b) (6)	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '2020'	System	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '2020'	System	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:08:32

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinus operation, LLT: Sinus operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 06:10:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 06:10:29
Data point term sent to Coder	System	09 Nov 2020 16:36:08
User entered 'Multiple Sinus Surgeries'	(b) (4), (b) (6) (b) (4)	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '09:12'	(b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 09:12'	System	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '63' in reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:17:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 13:55:59
User entered '63' in	(b) (4), (b) (6)	11 Sep 2020 16:08:12
DataPoint set to visible.	System	11 Sep 2020 14:27:03

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '218' lb reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:17:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 13:55:59
User entered '218' lb	(b) (4), (b) (6)	11 Sep 2020 16:08:12
DataPoint set to visible.	System	11 Sep 2020 14:27:03

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '38.69771'	System	14 Sep 2020 18:17:08
User entered empty.	System	14 Sep 2020 13:55:59
User entered '38.69771'	System	11 Sep 2020 16:08:12
DataPoint set to visible.	System	11 Sep 2020 14:27:03

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	14 Sep 2020 18:17:08
User entered empty.	System	14 Sep 2020 13:55:59
User entered 'kg/m2'	System	11 Sep 2020 16:08:12
DataPoint set to visible.	System	11 Sep 2020 14:27:03

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 13:55:59
User entered '96.7' F	(b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 13:55:59
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 13:55:59
User entered '62'	(b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 13:55:59
User entered '16'	(b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 13:55:59
User entered '113'	(b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 13:55:59
User entered '70'	(b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 15:59:50

US3602030

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 15:59:50

US3602030

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:06:54

US3602030

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:32

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User closed query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	14 Sep 2020 13:56:56
User opened query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	11 Sep 2020 16:06:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:06:54

US3602030

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:32

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:06:54

US3602030

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:32

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:06:54

US3602030

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:32

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:06:54

US3602030

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:32

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:06:54

US3602030

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:32

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 13:56:56
User entered 'UN UNK 2020'	(b) (4), (b) (6)	11 Sep 2020 16:06:54

US3602030

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:32

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:06:54

US3602030

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:08:25

US3602030

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:08:25

US3602030

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	(b) (4), (b) (6)	11 Sep 2020 16:08:25

US3602030

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	11 Sep 2020 16:08:25

US3602030

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:08:25

US3602030

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:08:25

US3602030

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:08:25

US3602030

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 16:08:25

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

[Specify](#)

Audit	User	Time (GMT)
User entered 'Admin, not exposed to people, remote'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

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 '1'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:32

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:04:29

US3602030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:04:29

US3602030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Sep 2020 16:04:29

US3602030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	11 Sep 2020 16:04:29

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Sep 2020 13:54:49

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '113375'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Sep 2020 13:54:49

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Sep 2020 13:54:49

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:32

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)	11 Sep 2020 16:05:12

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:05:12

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:05:12

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:32

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:05:12

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:32

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:05:12

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 14:03:40
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 06:07:34
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:07:33

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:32

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:16:48
User entered '63' in	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:32

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:16:48
User entered '218' lb	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:32

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:16:48
User entered '63' in	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:32

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:16:48
User entered '218' lb	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '09:12'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 09:12'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 10:33:04
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	(b) (4), (b) (6)	17 Sep 2020 12:55:18
answered with 'This is NCS per the provider' (Site from System).		
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:33:06
User entered '96.7' F	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '62'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '113'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '70'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:32

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:16:48
User entered '63' in	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:32

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:16:48
User entered '218' lb	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '12:00'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.6' F	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '67'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '129'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '71'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:16:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:04:38

US3602030

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:16:22
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:04:38

US3602030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Re-query: Since, subject is screened, enrolled, randomized, and dose on the same day, please update this data point as NO.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 09:07:04
Query 'Per CDM: Re-query: Since, subject is screened, enrolled, randomized, and dose on the same day, please update this data point as NO.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 13:11:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 13:11:06
User opened query 'Per CDM: Re-query: Since, subject is screened, enrolled, randomized, and dose on the same day, please update this data point as NO.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 10:33:55
User closed query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 10:33:55
Query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:32:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 12:54:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 14:53:12
User opened query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 11:11:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:10:30

US3602030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 13:11:06
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 12:54:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 14:53:12
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:10:30

US3602030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

[Test performed](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 13:11:06
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 12:54:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 14:53:12
User entered 'Urine (URINE)'	(b) (4), (b) (6)	11 Sep 2020 16:10:30

US3602030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

[Result](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 13:11:06
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 12:54:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 14:53:12
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	11 Sep 2020 16:10:30

US3602030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please consider entering "No" for this field as screening and V1D1 have occurred on the same day.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:10:26
Query 'Per CDM: Please consider entering "No" for this field as screening and V1D1 have occurred on the same day.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:08:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:08:34
User opened query 'Per CDM: Please consider entering "No" for this field as screening and V1D1 have occurred on the same day.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 08:19:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 13:11:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 12:54:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 14:53:12
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:10:30

US3602030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:10:30

US3602030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:10:30

US3602030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 16:10:30

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

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)	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '11:30'	(b) (4), (b) (6)	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:30'	System	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:10:45

US3602030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:10:45

US3602030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:12'	(b) (4), (b) (6)	11 Sep 2020 16:10:45

US3602030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 09:12'	System	11 Sep 2020 16:10:45

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:08:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:10:59

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:32

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Sep 2020 16:10:59

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:10:59

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:12'	(b) (4), (b) (6)	11 Sep 2020 16:10:59

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 09:12'	System	11 Sep 2020 16:10:59

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:32

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Sep 2020 16:10:59

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:10:59

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:10:59

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 16:10:59

US3602030

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:11:05

US3602030

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:11:05

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:02:20', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1efc487e-1e5f-4233-a6d2-f9fc1c6789cd'	System	11 Sep 2020 16:05:38
User entered 'Yes (Y)'	System	11 Sep 2020 16:05:38

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:02:24', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1efc487e-1e5f-4233-a6d2-f9fc1c6789cd'	System	11 Sep 2020 16:05:38
User entered '98.6'	System	11 Sep 2020 16:05:38

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:02:30', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1efc487e-1e5f-4233-a6d2-f9fc1c6789cd'	System	11 Sep 2020 16:05:38
User entered 'No (N)'	System	11 Sep 2020 16:05:38

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:02:34', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1efc487e-1e5f-4233-a6d2-f9fc1c6789cd'	System	11 Sep 2020 16:05:38
User entered '11 Sep 2020 12:02'	System	11 Sep 2020 16:05:38

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:50'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 14:20'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:20:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '6ecfd982-9efd-4c4c-bee6-daed648b8759'	System	11 Sep 2020 23:21:13
User entered 'Yes (Y)'	System	11 Sep 2020 23:21:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:04', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '6ecfd982-9efd-4c4c-bee6-daed648b8759'	System	11 Sep 2020 23:21:13
User entered '97.3'	System	11 Sep 2020 23:21:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:08', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '6ecfd982-9efd-4c4c-bee6-daed648b8759'	System	11 Sep 2020 23:21:13
User entered 'No (N)'	System	11 Sep 2020 23:21:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:12', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '6ecfd982-9efd-4c4c-bee6-daed648b8759'	System	11 Sep 2020 23:21:13
User entered '11 Sep 2020 19:21'	System	11 Sep 2020 23:21:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 15:15'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 2'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:10:28', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e6528f49-a2ee-426d-a772-0fae8f4f04d2'	System	12 Sep 2020 18:10:41
User entered 'Yes (Y)'	System	12 Sep 2020 18:10:41

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:10:33', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e6528f49-a2ee-426d-a772-0fae8f4f04d2'	System	12 Sep 2020 18:10:41
User entered '98.2'	System	12 Sep 2020 18:10:41

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:10:35', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e6528f49-a2ee-426d-a772-0fae8f4f04d2'	System	12 Sep 2020 18:10:41
User entered 'No (N)'	System	12 Sep 2020 18:10:41

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:10:38', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e6528f49-a2ee-426d-a772-0fae8f4f04d2'	System	12 Sep 2020 18:10:41
User entered '12 Sep 2020 14:10'	System	12 Sep 2020 18:10:41

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 3'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:20:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9629adeb-42da-455a-b7c0-d208f4d63a45'	System	13 Sep 2020 17:21:16
User entered 'Yes (Y)'	System	13 Sep 2020 17:21:16

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:03', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9629adeb-42da-455a-b7c0-d208f4d63a45'	System	13 Sep 2020 17:21:16
User entered '98.2'	System	13 Sep 2020 17:21:16

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:06', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9629adeb-42da-455a-b7c0-d208f4d63a45'	System	13 Sep 2020 17:21:16
User entered 'No (N)'	System	13 Sep 2020 17:21:16

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:08', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9629adeb-42da-455a-b7c0-d208f4d63a45'	System	13 Sep 2020 17:21:16
User entered '13 Sep 2020 13:21'	System	13 Sep 2020 17:21:16

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 4'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:12', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9201c8f6-bfd5-4634-81bb-652af2554451'	System	14 Sep 2020 16:41:39
User entered 'Yes (Y)'	System	14 Sep 2020 16:41:39

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:15', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9201c8f6-bfd5-4634-81bb-652af2554451'	System	14 Sep 2020 16:41:39
User entered '98.5'	System	14 Sep 2020 16:41:39

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:18', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9201c8f6-bfd5-4634-81bb-652af2554451'	System	14 Sep 2020 16:41:39
User entered 'No (N)'	System	14 Sep 2020 16:41:39

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:20', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9201c8f6-bfd5-4634-81bb-652af2554451'	System	14 Sep 2020 16:41:39
User entered '14 Sep 2020 12:41'	System	14 Sep 2020 16:41:39

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 5'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:20:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '0a3ba6da-50f1-43f1-99ca-354dfad0fd22'	System	15 Sep 2020 17:21:15
User entered 'Yes (Y)'	System	15 Sep 2020 17:21:15

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:21:08', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '0a3ba6da-50f1-43f1-99ca-354dfad0fd22'	System	15 Sep 2020 17:21:15
User entered '98.3'	System	15 Sep 2020 17:21:15

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:21:11', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '0a3ba6da-50f1-43f1-99ca-354dfad0fd22'	System	15 Sep 2020 17:21:15
User entered 'No (N)'	System	15 Sep 2020 17:21:15

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:21:13', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '0a3ba6da-50f1-43f1-99ca-354dfad0fd22'	System	15 Sep 2020 17:21:15
User entered '15 Sep 2020 13:21'	System	15 Sep 2020 17:21:15

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 6'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:15:45', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e2f4fc87-3452-4491-a83a-67b40f18752a'	System	16 Sep 2020 16:15:56
User entered 'Yes (Y)'	System	16 Sep 2020 16:15:56

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:15:49', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e2f4fc87-3452-4491-a83a-67b40f18752a'	System	16 Sep 2020 16:15:56
User entered '98.4'	System	16 Sep 2020 16:15:56

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:15:51', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e2f4fc87-3452-4491-a83a-67b40f18752a'	System	16 Sep 2020 16:15:56
User entered 'No (N)'	System	16 Sep 2020 16:15:56

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:15:54', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e2f4fc87-3452-4491-a83a-67b40f18752a'	System	16 Sep 2020 16:15:56
User entered '16 Sep 2020 12:15'	System	16 Sep 2020 16:15:56

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 7'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:29', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4aa8669d-3bb8-43e1-91df-ecfbb6cef837'	System	17 Sep 2020 16:24:37
User entered 'Yes (Y)'	System	17 Sep 2020 16:24:37

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:32', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4aa8669d-3bb8-43e1-91df-ecfbb6cef837'	System	17 Sep 2020 16:24:37
User entered '98.6'	System	17 Sep 2020 16:24:37

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:34', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4aa8669d-3bb8-43e1-91df-ecfbb6cef837'	System	17 Sep 2020 16:24:37
User entered 'No (N)'	System	17 Sep 2020 16:24:37

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:37', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4aa8669d-3bb8-43e1-91df-ecfbb6cef837'	System	17 Sep 2020 16:24:37
User entered '17 Sep 2020 12:24'	System	17 Sep 2020 16:24:37

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-11T12:02:44', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'b4e8a0e6-fb2a-4688-9fbc-ad326c6059cc'	System	11 Sep 2020 16:06:24
User entered 'None (1)'	System	11 Sep 2020 16:06:24

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:10', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'b4e8a0e6-fb2a-4688-9fbc-ad326c6059cc'	System	11 Sep 2020 16:06:24
User entered 'No (N)'	System	11 Sep 2020 16:06:24

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:17', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'b4e8a0e6-fb2a-4688-9fbc-ad326c6059cc'	System	11 Sep 2020 16:06:24
User entered 'No (N)'	System	11 Sep 2020 16:06:24

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:26', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'b4e8a0e6-fb2a-4688-9fbc-ad326c6059cc'	System	11 Sep 2020 16:06:24
User entered 'None (1)'	System	11 Sep 2020 16:06:24

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:30', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'b4e8a0e6-fb2a-4688-9fbc-ad326c6059cc'	System	11 Sep 2020 16:06:24
User entered '11 Sep 2020 12:03'	System	11 Sep 2020 16:06:24

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:50'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 14:20'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:18', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1c629fa9-8c02-403a-83df-2e00c3ce830c'	System	11 Sep 2020 23:21:46
User entered 'None (1)'	System	11 Sep 2020 23:21:46

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:21', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1c629fa9-8c02-403a-83df-2e00c3ce830c'	System	11 Sep 2020 23:21:46
User entered 'No (N)'	System	11 Sep 2020 23:21:46

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:30', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1c629fa9-8c02-403a-83df-2e00c3ce830c'	System	11 Sep 2020 23:21:46
User entered 'No (N)'	System	11 Sep 2020 23:21:46

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:36', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1c629fa9-8c02-403a-83df-2e00c3ce830c'	System	11 Sep 2020 23:21:46
User entered 'None (1)'	System	11 Sep 2020 23:21:46

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:43', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1c629fa9-8c02-403a-83df-2e00c3ce830c'	System	11 Sep 2020 23:21:46
User entered '11 Sep 2020 19:21'	System	11 Sep 2020 23:21:46

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 15:15'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 2'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-12T14:09:22', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2abea7fa-fe70-4b3c-a34f-deb0302a182e'	System	12 Sep 2020 18:09:47
User entered 'None (1)'	System	12 Sep 2020 18:09:47

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:09:25', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2abea7fa-fe70-4b3c-a34f-deb0302a182e'	System	12 Sep 2020 18:09:47
User entered 'No (N)'	System	12 Sep 2020 18:09:47

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:09:37', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2abea7fa-fe70-4b3c-a34f-deb0302a182e'	System	12 Sep 2020 18:09:47
User entered 'No (N)'	System	12 Sep 2020 18:09:47

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-12T14:09:40', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2abea7fa-fe70-4b3c-a34f-deb0302a182e'	System	12 Sep 2020 18:09:47
User entered 'None (1)'	System	12 Sep 2020 18:09:47

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:09:44', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2abea7fa-fe70-4b3c-a34f-deb0302a182e'	System	12 Sep 2020 18:09:47
User entered '12 Sep 2020 14:09'	System	12 Sep 2020 18:09:47

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 3'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:19', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9790e08b-9958-4f34-b879-6523acaaa47f'	System	13 Sep 2020 17:21:48
User entered 'None (1)'	System	13 Sep 2020 17:21:48

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:22', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9790e08b-9958-4f34-b879-6523acaaa47f'	System	13 Sep 2020 17:21:48
User entered 'No (N)'	System	13 Sep 2020 17:21:48

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:24', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9790e08b-9958-4f34-b879-6523acaaa47f'	System	13 Sep 2020 17:21:48
User entered 'No (N)'	System	13 Sep 2020 17:21:48

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:34', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9790e08b-9958-4f34-b879-6523acaaa47f'	System	13 Sep 2020 17:21:48
User entered 'None (1)'	System	13 Sep 2020 17:21:48

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:37', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9790e08b-9958-4f34-b879-6523acaaa47f'	System	13 Sep 2020 17:21:48
User entered '13 Sep 2020 13:21'	System	13 Sep 2020 17:21:48

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 4'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:24', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'dc1fa60c-a5dc-4607-a6d2-cb24e89880ea'	System	14 Sep 2020 16:41:50
User entered 'None (1)'	System	14 Sep 2020 16:41:50

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:29', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'dc1fa60c-a5dc-4607-a6d2-cb24e89880ea'	System	14 Sep 2020 16:41:50
User entered 'No (N)'	System	14 Sep 2020 16:41:50

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:34', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'dc1fa60c-a5dc-4607-a6d2-cb24e89880ea'	System	14 Sep 2020 16:41:50
User entered 'No (N)'	System	14 Sep 2020 16:41:50

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:40', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'dc1fa60c-a5dc-4607-a6d2-cb24e89880ea'	System	14 Sep 2020 16:41:50
User entered 'None (1)'	System	14 Sep 2020 16:41:50

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:45', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'dc1fa60c-a5dc-4607-a6d2-cb24e89880ea'	System	14 Sep 2020 16:41:50
User entered '14 Sep 2020 12:41'	System	14 Sep 2020 16:41:50

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 5'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-15T13:20:25', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '94fa49c7-2f90-4e88-8228-d034e609b3cf'	System	15 Sep 2020 17:20:54
User entered 'None (1)'	System	15 Sep 2020 17:20:54

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:20:27', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '94fa49c7-2f90-4e88-8228-d034e609b3cf'	System	15 Sep 2020 17:20:54
User entered 'No (N)'	System	15 Sep 2020 17:20:54

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:20:33', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '94fa49c7-2f90-4e88-8228-d034e609b3cf'	System	15 Sep 2020 17:20:54
User entered 'No (N)'	System	15 Sep 2020 17:20:54

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-15T13:20:51', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '94fa49c7-2f90-4e88-8228-d034e609b3cf'	System	15 Sep 2020 17:20:54
User entered 'None (1)'	System	15 Sep 2020 17:20:54

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:20:54', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '94fa49c7-2f90-4e88-8228-d034e609b3cf'	System	15 Sep 2020 17:20:54
User entered '15 Sep 2020 13:20'	System	15 Sep 2020 17:20:54

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 6'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-16T12:15:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '8849661b-3712-4954-9b62-57124bccdf92'	System	16 Sep 2020 16:16:14
User entered 'None (1)'	System	16 Sep 2020 16:16:14

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:01', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '8849661b-3712-4954-9b62-57124bccdf92'	System	16 Sep 2020 16:16:14
User entered 'No (N)'	System	16 Sep 2020 16:16:14

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:04', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '8849661b-3712-4954-9b62-57124bccdf92'	System	16 Sep 2020 16:16:14
User entered 'No (N)'	System	16 Sep 2020 16:16:14

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:12', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '8849661b-3712-4954-9b62-57124bccdf92'	System	16 Sep 2020 16:16:14
User entered 'None (1)'	System	16 Sep 2020 16:16:14

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:14', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '8849661b-3712-4954-9b62-57124bccdf92'	System	16 Sep 2020 16:16:14
User entered '16 Sep 2020 12:16'	System	16 Sep 2020 16:16:14

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 7'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:40', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4073ab8d-6047-4d37-b750-889b39e3ed78'	System	17 Sep 2020 16:24:57
User entered 'None (1)'	System	17 Sep 2020 16:24:57

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:42', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4073ab8d-6047-4d37-b750-889b39e3ed78'	System	17 Sep 2020 16:24:57
User entered 'No (N)'	System	17 Sep 2020 16:24:57

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:44', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4073ab8d-6047-4d37-b750-889b39e3ed78'	System	17 Sep 2020 16:24:57
User entered 'No (N)'	System	17 Sep 2020 16:24:57

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:51', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4073ab8d-6047-4d37-b750-889b39e3ed78'	System	17 Sep 2020 16:24:57
User entered 'None (1)'	System	17 Sep 2020 16:24:57

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:54', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4073ab8d-6047-4d37-b750-889b39e3ed78'	System	17 Sep 2020 16:24:57
User entered '17 Sep 2020 12:24'	System	17 Sep 2020 16:24:57

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:37', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4ceaa4dc-175a-4bb1-8376-11d2991b2728'	System	11 Sep 2020 16:06:42
User entered 'None (0)'	System	11 Sep 2020 16:06:42

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:40', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4ceaa4dc-175a-4bb1-8376-11d2991b2728'	System	11 Sep 2020 16:06:42
User entered 'None (0)'	System	11 Sep 2020 16:06:42

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:43', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4ceaa4dc-175a-4bb1-8376-11d2991b2728'	System	11 Sep 2020 16:06:42
User entered 'None (0)'	System	11 Sep 2020 16:06:42

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:46', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4ceaa4dc-175a-4bb1-8376-11d2991b2728'	System	11 Sep 2020 16:06:42
User entered 'None (0)'	System	11 Sep 2020 16:06:42

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:48', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4ceaa4dc-175a-4bb1-8376-11d2991b2728'	System	11 Sep 2020 16:06:42
User entered 'None (0)'	System	11 Sep 2020 16:06:42

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:51', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4ceaa4dc-175a-4bb1-8376-11d2991b2728'	System	11 Sep 2020 16:06:42
User entered 'None (0)'	System	11 Sep 2020 16:06:42

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:54', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4ceaa4dc-175a-4bb1-8376-11d2991b2728'	System	11 Sep 2020 16:06:42
User entered 'No (N)'	System	11 Sep 2020 16:06:42

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:56', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4ceaa4dc-175a-4bb1-8376-11d2991b2728'	System	11 Sep 2020 16:06:42
User entered '11 Sep 2020 12:03'	System	11 Sep 2020 16:06:42

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:50'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 14:20'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:47', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'a716633b-e56d-4619-9416-b48618a906e0'	System	11 Sep 2020 23:22:09
User entered 'None (0)'	System	11 Sep 2020 23:22:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:50', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'a716633b-e56d-4619-9416-b48618a906e0'	System	11 Sep 2020 23:22:09
User entered 'None (0)'	System	11 Sep 2020 23:22:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:52', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'a716633b-e56d-4619-9416-b48618a906e0'	System	11 Sep 2020 23:22:09
User entered 'None (0)'	System	11 Sep 2020 23:22:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:55', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'a716633b-e56d-4619-9416-b48618a906e0'	System	11 Sep 2020 23:22:09
User entered 'None (0)'	System	11 Sep 2020 23:22:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:57', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'a716633b-e56d-4619-9416-b48618a906e0'	System	11 Sep 2020 23:22:09
User entered 'None (0)'	System	11 Sep 2020 23:22:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'a716633b-e56d-4619-9416-b48618a906e0'	System	11 Sep 2020 23:22:09
User entered 'None (0)'	System	11 Sep 2020 23:22:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-11T19:22:02', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'a716633b-e56d-4619-9416-b48618a906e0'	System	11 Sep 2020 23:22:09
User entered 'No (N)'	System	11 Sep 2020 23:22:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:22:05', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'a716633b-e56d-4619-9416-b48618a906e0'	System	11 Sep 2020 23:22:09
User entered '11 Sep 2020 19:22'	System	11 Sep 2020 23:22:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 15:15'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 2'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:09:48', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '09af8554-05a3-4e11-8d4f-0b384eaaa7e3'	System	12 Sep 2020 18:10:09
User entered 'None (0)'	System	12 Sep 2020 18:10:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:09:50', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '09af8554-05a3-4e11-8d4f-0b384eaaa7e3'	System	12 Sep 2020 18:10:09
User entered 'None (0)'	System	12 Sep 2020 18:10:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:09:55', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '09af8554-05a3-4e11-8d4f-0b384eaaa7e3'	System	12 Sep 2020 18:10:09
User entered 'None (0)'	System	12 Sep 2020 18:10:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:09:58', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '09af8554-05a3-4e11-8d4f-0b384eaaa7e3'	System	12 Sep 2020 18:10:09
User entered 'None (0)'	System	12 Sep 2020 18:10:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:10:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '09af8554-05a3-4e11-8d4f-0b384eaaa7e3'	System	12 Sep 2020 18:10:09
User entered 'None (0)'	System	12 Sep 2020 18:10:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:10:02', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '09af8554-05a3-4e11-8d4f-0b384eaaa7e3'	System	12 Sep 2020 18:10:09
User entered 'None (0)'	System	12 Sep 2020 18:10:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-12T14:10:04', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '09af8554-05a3-4e11-8d4f-0b384eaaa7e3'	System	12 Sep 2020 18:10:09
User entered 'No (N)'	System	12 Sep 2020 18:10:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:10:08', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '09af8554-05a3-4e11-8d4f-0b384eaaa7e3'	System	12 Sep 2020 18:10:09
User entered '12 Sep 2020 14:10'	System	12 Sep 2020 18:10:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 3'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:41', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2bcae4b9-f404-47e9-8c43-0dfeaec39b21'	System	13 Sep 2020 17:22:11
User entered 'None (0)'	System	13 Sep 2020 17:22:11

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:42', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2bcae4b9-f404-47e9-8c43-0dfeaec39b21'	System	13 Sep 2020 17:22:11
User entered 'None (0)'	System	13 Sep 2020 17:22:11

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:44', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2bcae4b9-f404-47e9-8c43-0dfeaec39b21'	System	13 Sep 2020 17:22:11
User entered 'None (0)'	System	13 Sep 2020 17:22:11

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:46', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2bcae4b9-f404-47e9-8c43-0dfeaec39b21'	System	13 Sep 2020 17:22:11
User entered 'None (0)'	System	13 Sep 2020 17:22:11

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:48', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2bcae4b9-f404-47e9-8c43-0dfeaec39b21'	System	13 Sep 2020 17:22:11
User entered 'None (0)'	System	13 Sep 2020 17:22:11

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:50', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2bcae4b9-f404-47e9-8c43-0dfeaec39b21'	System	13 Sep 2020 17:22:11
User entered 'None (0)'	System	13 Sep 2020 17:22:11

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:52', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2bcae4b9-f404-47e9-8c43-0dfeaec39b21'	System	13 Sep 2020 17:22:11
User entered 'No (N)'	System	13 Sep 2020 17:22:11

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:56', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2bcae4b9-f404-47e9-8c43-0dfeaec39b21'	System	13 Sep 2020 17:22:11
User entered '13 Sep 2020 13:21'	System	13 Sep 2020 17:22:11

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 4'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:54', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3fd72fc9-160a-469d-bde5-a3957aa8a7eb'	System	14 Sep 2020 16:42:18
User entered 'None (0)'	System	14 Sep 2020 16:42:18

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:57', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3fd72fc9-160a-469d-bde5-a3957aa8a7eb'	System	14 Sep 2020 16:42:18
User entered 'None (0)'	System	14 Sep 2020 16:42:18

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:42:01', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3fd72fc9-160a-469d-bde5-a3957aa8a7eb'	System	14 Sep 2020 16:42:18
User entered 'None (0)'	System	14 Sep 2020 16:42:18

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:42:09', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3fd72fc9-160a-469d-bde5-a3957aa8a7eb'	System	14 Sep 2020 16:42:18
User entered 'None (0)'	System	14 Sep 2020 16:42:18

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:42:10', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3fd72fc9-160a-469d-bde5-a3957aa8a7eb'	System	14 Sep 2020 16:42:18
User entered 'None (0)'	System	14 Sep 2020 16:42:18

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:42:12', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3fd72fc9-160a-469d-bde5-a3957aa8a7eb'	System	14 Sep 2020 16:42:18
User entered 'None (0)'	System	14 Sep 2020 16:42:18

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-14T12:42:15', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3fd72fc9-160a-469d-bde5-a3957aa8a7eb'	System	14 Sep 2020 16:42:18
User entered 'No (N)'	System	14 Sep 2020 16:42:18

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:42:18', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3fd72fc9-160a-469d-bde5-a3957aa8a7eb'	System	14 Sep 2020 16:42:18
User entered '14 Sep 2020 12:42'	System	14 Sep 2020 16:42:18

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 5'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:19:43', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c806ae03-27c0-46db-89b3-6f509665d328'	System	15 Sep 2020 17:19:59
User entered 'None (0)'	System	15 Sep 2020 17:19:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:19:45', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c806ae03-27c0-46db-89b3-6f509665d328'	System	15 Sep 2020 17:19:59
User entered 'None (0)'	System	15 Sep 2020 17:19:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:19:46', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c806ae03-27c0-46db-89b3-6f509665d328'	System	15 Sep 2020 17:19:59
User entered 'None (0)'	System	15 Sep 2020 17:19:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:19:51', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c806ae03-27c0-46db-89b3-6f509665d328'	System	15 Sep 2020 17:19:59
User entered 'None (0)'	System	15 Sep 2020 17:19:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:19:53', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c806ae03-27c0-46db-89b3-6f509665d328'	System	15 Sep 2020 17:19:59
User entered 'None (0)'	System	15 Sep 2020 17:19:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:19:55', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c806ae03-27c0-46db-89b3-6f509665d328'	System	15 Sep 2020 17:19:59
User entered 'None (0)'	System	15 Sep 2020 17:19:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-15T13:19:57', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c806ae03-27c0-46db-89b3-6f509665d328'	System	15 Sep 2020 17:19:59
User entered 'No (N)'	System	15 Sep 2020 17:19:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:19:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c806ae03-27c0-46db-89b3-6f509665d328'	System	15 Sep 2020 17:19:59
User entered '15 Sep 2020 13:19'	System	15 Sep 2020 17:19:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 6'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:18', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f00f4b0-460c-4994-861e-c8f922b5e32f'	System	16 Sep 2020 16:16:32
User entered 'None (0)'	System	16 Sep 2020 16:16:32

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:19', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f00f4b0-460c-4994-861e-c8f922b5e32f'	System	16 Sep 2020 16:16:32
User entered 'None (0)'	System	16 Sep 2020 16:16:32

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:21', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f00f4b0-460c-4994-861e-c8f922b5e32f'	System	16 Sep 2020 16:16:32
User entered 'None (0)'	System	16 Sep 2020 16:16:32

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:23', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f00f4b0-460c-4994-861e-c8f922b5e32f'	System	16 Sep 2020 16:16:32
User entered 'None (0)'	System	16 Sep 2020 16:16:32

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:24', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f00f4b0-460c-4994-861e-c8f922b5e32f'	System	16 Sep 2020 16:16:32
User entered 'None (0)'	System	16 Sep 2020 16:16:32

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:26', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f00f4b0-460c-4994-861e-c8f922b5e32f'	System	16 Sep 2020 16:16:32
User entered 'None (0)'	System	16 Sep 2020 16:16:32

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:28', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f00f4b0-460c-4994-861e-c8f922b5e32f'	System	16 Sep 2020 16:16:32
User entered 'No (N)'	System	16 Sep 2020 16:16:32

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:31', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f00f4b0-460c-4994-861e-c8f922b5e32f'	System	16 Sep 2020 16:16:32
User entered '16 Sep 2020 12:16'	System	16 Sep 2020 16:16:32

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 7'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:58', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7ab5609a-7431-441d-9fd1-192f0b7a6180'	System	17 Sep 2020 16:25:13
User entered 'None (0)'	System	17 Sep 2020 16:25:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7ab5609a-7431-441d-9fd1-192f0b7a6180'	System	17 Sep 2020 16:25:13
User entered 'None (0)'	System	17 Sep 2020 16:25:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:25:01', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7ab5609a-7431-441d-9fd1-192f0b7a6180'	System	17 Sep 2020 16:25:13
User entered 'None (0)'	System	17 Sep 2020 16:25:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:25:02', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7ab5609a-7431-441d-9fd1-192f0b7a6180'	System	17 Sep 2020 16:25:13
User entered 'None (0)'	System	17 Sep 2020 16:25:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:25:03', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7ab5609a-7431-441d-9fd1-192f0b7a6180'	System	17 Sep 2020 16:25:13
User entered 'None (0)'	System	17 Sep 2020 16:25:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:25:05', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7ab5609a-7431-441d-9fd1-192f0b7a6180'	System	17 Sep 2020 16:25:13
User entered 'None (0)'	System	17 Sep 2020 16:25:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-09-17T12:25:07', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7ab5609a-7431-441d-9fd1-192f0b7a6180'	System	17 Sep 2020 16:25:13
User entered 'No (N)'	System	17 Sep 2020 16:25:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:25:13', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7ab5609a-7431-441d-9fd1-192f0b7a6180'	System	17 Sep 2020 16:25:13
User entered '17 Sep 2020 12:25'	System	17 Sep 2020 16:25:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 15:16:02

US3602030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '19 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 15:16:02

US3602030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 15:16:02

US3602030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:16:02

US3602030

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 15:16:06

US3602030

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 15:16:06

US3602030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 17:57:32

US3602030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '25 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 17:57:32

US3602030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Sep 2020 17:57:32

US3602030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 17:57:32

US3602030

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 17:57:08

US3602030

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 17:57:08

US3602030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 20:49:32

US3602030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '2 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 20:49:32

US3602030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 20:49:32

US3602030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 20:49:32

US3602030

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 20:49:35

US3602030

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 20:49:35

US3602030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:25:06

US3602030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 14:25:06

US3602030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Oct 2020 14:25:06

US3602030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	16 Oct 2020 14:25:06

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '08:55'	(b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 08:55'	System	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	(b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Forehead'	(b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

Pulse (xxx)

Audit	User	Time (GMT)
User entered '70'	(b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '114'	(b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '84'	(b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '11:05'	(b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:05'	System	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	(b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Temporal'	(b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '67'	(b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '104'	(b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '77'	(b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:26:36

US3602030

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 14:26:36

US3602030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:26:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 14:26:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	(b) (4), (b) (6)	16 Oct 2020 14:26:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	16 Oct 2020 14:26:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 14:26:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:26:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:26:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 14:26:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

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)	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '10:36'	(b) (4), (b) (6)	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 10:36'	System	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:26:16

US3602030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 14:26:16

US3602030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:06'	(b) (4), (b) (6)	16 Oct 2020 14:26:16

US3602030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 09:06'	System	16 Oct 2020 14:26:16

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:08:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 14:26:27

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:32

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Oct 2020 14:26:27

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:26:27

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:06'	(b) (4), (b) (6)	16 Oct 2020 14:26:27

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 09:06'	System	16 Oct 2020 14:26:27

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:32

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Oct 2020 14:26:27

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 14:26:27

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:26:27

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 14:26:27

US3602030

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:26:30

US3602030

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:26:30

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:10:16', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '48fcc636-08e2-4821-ad7d-2a3724c61b42'	System	16 Oct 2020 15:10:30
User entered 'Yes (Y)'	System	16 Oct 2020 15:10:30

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:10:21', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '48fcc636-08e2-4821-ad7d-2a3724c61b42'	System	16 Oct 2020 15:10:30
User entered '97.9'	System	16 Oct 2020 15:10:30

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:10:24', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '48fcc636-08e2-4821-ad7d-2a3724c61b42'	System	16 Oct 2020 15:10:30
User entered 'No (N)'	System	16 Oct 2020 15:10:30

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:10:28', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '48fcc636-08e2-4821-ad7d-2a3724c61b42'	System	16 Oct 2020 15:10:30
User entered '16 Oct 2020 11:10'	System	16 Oct 2020 15:10:30

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 10:56'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 13:26'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:33:35', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'f10d8f6a-383f-41f9-8146-8612a973cb46'	System	16 Oct 2020 22:33:52
User entered 'Yes (Y)'	System	16 Oct 2020 22:33:52

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:33:43', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'f10d8f6a-383f-41f9-8146-8612a973cb46'	System	16 Oct 2020 22:33:52
User entered '98.8'	System	16 Oct 2020 22:33:52

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:33:45', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'f10d8f6a-383f-41f9-8146-8612a973cb46'	System	16 Oct 2020 22:33:52
User entered 'No (N)'	System	16 Oct 2020 22:33:52

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:33:49', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'f10d8f6a-383f-41f9-8146-8612a973cb46'	System	16 Oct 2020 22:33:52
User entered '16 Oct 2020 18:33'	System	16 Oct 2020 22:33:52

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 14:21'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 2'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:40:42', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2428ac72-ef34-4f4b-8aee-ed873032b089'	System	17 Oct 2020 19:40:54
User entered 'Yes (Y)'	System	17 Oct 2020 19:40:54

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:40:45', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2428ac72-ef34-4f4b-8aee-ed873032b089'	System	17 Oct 2020 19:40:54
User entered '97.9'	System	17 Oct 2020 19:40:54

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:40:49', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2428ac72-ef34-4f4b-8aee-ed873032b089'	System	17 Oct 2020 19:40:54
User entered 'No (N)'	System	17 Oct 2020 19:40:54

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:40:52', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2428ac72-ef34-4f4b-8aee-ed873032b089' User entered '17 Oct 2020 15:40'	System	17 Oct 2020 19:40:54
	System	17 Oct 2020 19:40:54

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 3'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:12', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '92bb57e0-9981-416f-87ad-af0b324d464d'	System	18 Oct 2020 18:14:21
User entered 'Yes (Y)'	System	18 Oct 2020 18:14:21

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:16', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '92bb57e0-9981-416f-87ad-af0b324d464d'	System	18 Oct 2020 18:14:21
User entered '97.9'	System	18 Oct 2020 18:14:21

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:19', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '92bb57e0-9981-416f-87ad-af0b324d464d'	System	18 Oct 2020 18:14:21
User entered 'No (N)'	System	18 Oct 2020 18:14:21

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:21', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '92bb57e0-9981-416f-87ad-af0b324d464d'	System	18 Oct 2020 18:14:21
User entered '18 Oct 2020 14:14'	System	18 Oct 2020 18:14:21

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 4'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:17:35', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '590a2eb6-ec5f-4e5a-9fcc-c534a67c8b77'	System	19 Oct 2020 19:17:48
User entered 'Yes (Y)'	System	19 Oct 2020 19:17:48

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:17:38', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '590a2eb6-ec5f-4e5a-9fcc-c534a67c8b77'	System	19 Oct 2020 19:17:48
User entered '98.7'	System	19 Oct 2020 19:17:48

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:17:41', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '590a2eb6-ec5f-4e5a-9fcc-c534a67c8b77'	System	19 Oct 2020 19:17:48
User entered 'No (N)'	System	19 Oct 2020 19:17:48

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:17:43', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '590a2eb6-ec5f-4e5a-9fcc-c534a67c8b77'	System	19 Oct 2020 19:17:48
User entered '19 Oct 2020 15:17'	System	19 Oct 2020 19:17:48

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 5'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:54', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'aa06b645-b3f8-484c-8c12-9015a47b8923'	System	20 Oct 2020 16:09:15
User entered 'Yes (Y)'	System	20 Oct 2020 16:09:15

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:57', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'aa06b645-b3f8-484c-8c12-9015a47b8923'	System	20 Oct 2020 16:09:15
User entered '98.5'	System	20 Oct 2020 16:09:15

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'aa06b645-b3f8-484c-8c12-9015a47b8923'	System	20 Oct 2020 16:09:15
User entered 'No (N)'	System	20 Oct 2020 16:09:15

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:09:12', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'aa06b645-b3f8-484c-8c12-9015a47b8923'	System	20 Oct 2020 16:09:15
User entered '20 Oct 2020 12:09'	System	20 Oct 2020 16:09:15

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 6'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:02:22', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '72aa5e9f-c537-483c-9951-36deb6530a63'	System	21 Oct 2020 18:02:40
User entered 'Yes (Y)'	System	21 Oct 2020 18:02:40

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:02:26', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '72aa5e9f-c537-483c-9951-36deb6530a63'	System	21 Oct 2020 18:02:40
User entered '98.6'	System	21 Oct 2020 18:02:40

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:02:29', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '72aa5e9f-c537-483c-9951-36deb6530a63'	System	21 Oct 2020 18:02:40
User entered 'No (N)'	System	21 Oct 2020 18:02:40

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:02:38', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '72aa5e9f-c537-483c-9951-36deb6530a63'	System	21 Oct 2020 18:02:40
User entered '21 Oct 2020 14:02'	System	21 Oct 2020 18:02:40

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 7'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:08', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'ff41a982-7777-43d9-ad6a-a07ec3eff02b'	System	22 Oct 2020 18:06:25
User entered 'Yes (Y)'	System	22 Oct 2020 18:06:25

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:11', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'ff41a982-7777-43d9-ad6a-a07ec3eff02b'	System	22 Oct 2020 18:06:25
User entered '98.2'	System	22 Oct 2020 18:06:25

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:14', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'ff41a982-7777-43d9-ad6a-a07ec3eff02b'	System	22 Oct 2020 18:06:25
User entered 'No (N)'	System	22 Oct 2020 18:06:25

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:24', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'ff41a982-7777-43d9-ad6a-a07ec3eff02b'	System	22 Oct 2020 18:06:25
User entered '22 Oct 2020 14:06'	System	22 Oct 2020 18:06:25

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-16T11:10:35', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '06f5acc5-09cd-444c-8230-a039b2068463'	System	16 Oct 2020 15:11:30
User entered 'None (1)'	System	16 Oct 2020 15:11:30

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:10:52', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '06f5acc5-09cd-444c-8230-a039b2068463'	System	16 Oct 2020 15:11:30
User entered 'No (N)'	System	16 Oct 2020 15:11:30

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:01', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '06f5acc5-09cd-444c-8230-a039b2068463'	System	16 Oct 2020 15:11:30
User entered 'No (N)'	System	16 Oct 2020 15:11:30

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:27', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '06f5acc5-09cd-444c-8230-a039b2068463'	System	16 Oct 2020 15:11:30
User entered 'None (1)'	System	16 Oct 2020 15:11:30

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:30', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '06f5acc5-09cd-444c-8230-a039b2068463'	System	16 Oct 2020 15:11:30
User entered '16 Oct 2020 11:11'	System	16 Oct 2020 15:11:30

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 10:56'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 13:26'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-16T18:33:55', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '970037c8-a6d7-49b2-b50e-6a26f09de257'	System	16 Oct 2020 22:34:50
User entered 'None (1)'	System	16 Oct 2020 22:34:50

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:34:18', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '970037c8-a6d7-49b2-b50e-6a26f09de257'	System	16 Oct 2020 22:34:50
User entered 'No (N)'	System	16 Oct 2020 22:34:50

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:34:32', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '970037c8-a6d7-49b2-b50e-6a26f09de257'	System	16 Oct 2020 22:34:50
User entered 'No (N)'	System	16 Oct 2020 22:34:50

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-16T18:34:42', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '970037c8-a6d7-49b2-b50e-6a26f09de257'	System	16 Oct 2020 22:34:50
User entered 'None (1)'	System	16 Oct 2020 22:34:50

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:34:47', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '970037c8-a6d7-49b2-b50e-6a26f09de257'	System	16 Oct 2020 22:34:50
User entered '16 Oct 2020 18:34'	System	16 Oct 2020 22:34:50

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 14:21'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 2'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:01', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e6bf9855-c536-4b8f-bdb8-ae2d9a256866'	System	17 Oct 2020 19:41:31
User entered 'None (1)'	System	17 Oct 2020 19:41:31

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:19', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e6bf9855-c536-4b8f-bdb8-ae2d9a256866'	System	17 Oct 2020 19:41:31
User entered 'No (N)'	System	17 Oct 2020 19:41:31

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:25', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e6bf9855-c536-4b8f-bdb8-ae2d9a256866'	System	17 Oct 2020 19:41:31
User entered 'No (N)'	System	17 Oct 2020 19:41:31

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:28', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e6bf9855-c536-4b8f-bdb8-ae2d9a256866'	System	17 Oct 2020 19:41:31
User entered 'None (1)'	System	17 Oct 2020 19:41:31

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:31', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e6bf9855-c536-4b8f-bdb8-ae2d9a256866'	System	17 Oct 2020 19:41:31
User entered '17 Oct 2020 15:41'	System	17 Oct 2020 19:41:31

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 3'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:26', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '89384f0c-0596-411c-999a-345e36fe54cb'	System	18 Oct 2020 18:14:54
User entered 'None (1)'	System	18 Oct 2020 18:14:54

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:49', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '89384f0c-0596-411c-999a-345e36fe54cb'	System	18 Oct 2020 18:14:54
User entered 'No (N)'	System	18 Oct 2020 18:14:54

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:51', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '89384f0c-0596-411c-999a-345e36fe54cb'	System	18 Oct 2020 18:14:54
User entered 'No (N)'	System	18 Oct 2020 18:14:54

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:53', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '89384f0c-0596-411c-999a-345e36fe54cb'	System	18 Oct 2020 18:14:54
User entered 'None (1)'	System	18 Oct 2020 18:14:54

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:55', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '89384f0c-0596-411c-999a-345e36fe54cb'	System	18 Oct 2020 18:14:54
User entered '18 Oct 2020 14:14'	System	18 Oct 2020 18:14:54

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 4'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-19T15:17:47', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '92da914c-03c1-4065-8ba6-b78802b92422'	System	19 Oct 2020 19:18:05
User entered 'None (1)'	System	19 Oct 2020 19:18:05

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:17:55', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '92da914c-03c1-4065-8ba6-b78802b92422'	System	19 Oct 2020 19:18:05
User entered 'No (N)'	System	19 Oct 2020 19:18:05

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:17:57', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '92da914c-03c1-4065-8ba6-b78802b92422'	System	19 Oct 2020 19:18:05
User entered 'No (N)'	System	19 Oct 2020 19:18:05

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-19T15:17:58', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '92da914c-03c1-4065-8ba6-b78802b92422'	System	19 Oct 2020 19:18:05
User entered 'None (1)'	System	19 Oct 2020 19:18:05

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:18:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '92da914c-03c1-4065-8ba6-b78802b92422'	System	19 Oct 2020 19:18:05
User entered '19 Oct 2020 15:18'	System	19 Oct 2020 19:18:05

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 5'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-20T12:07:55', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f709013-1345-47df-be0a-8c975aadabd3'	System	20 Oct 2020 16:08:19
User entered 'None (1)'	System	20 Oct 2020 16:08:19

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:02', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f709013-1345-47df-be0a-8c975aadabd3'	System	20 Oct 2020 16:08:19
User entered 'No (N)'	System	20 Oct 2020 16:08:19

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:06', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f709013-1345-47df-be0a-8c975aadabd3'	System	20 Oct 2020 16:08:19
User entered 'No (N)'	System	20 Oct 2020 16:08:19

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:08', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f709013-1345-47df-be0a-8c975aadabd3'	System	20 Oct 2020 16:08:19
User entered 'None (1)'	System	20 Oct 2020 16:08:19

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:17', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f709013-1345-47df-be0a-8c975aadabd3'	System	20 Oct 2020 16:08:19
User entered '20 Oct 2020 12:08'	System	20 Oct 2020 16:08:19

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 6'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-21T14:02:41', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '91c5b93f-fab0-4760-a241-4bb5aa22083b'	System	21 Oct 2020 18:02:57
User entered 'None (1)'	System	21 Oct 2020 18:02:57

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:02:44', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '91c5b93f-fab0-4760-a241-4bb5aa22083b'	System	21 Oct 2020 18:02:57
User entered 'No (N)'	System	21 Oct 2020 18:02:57

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:02:46', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '91c5b93f-fab0-4760-a241-4bb5aa22083b'	System	21 Oct 2020 18:02:57
User entered 'No (N)'	System	21 Oct 2020 18:02:57

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-21T14:02:53', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '91c5b93f-fab0-4760-a241-4bb5aa22083b'	System	21 Oct 2020 18:02:57
User entered 'None (1)'	System	21 Oct 2020 18:02:57

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:02:56', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '91c5b93f-fab0-4760-a241-4bb5aa22083b'	System	21 Oct 2020 18:02:57
User entered '21 Oct 2020 14:02'	System	21 Oct 2020 18:02:57

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 7'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:28', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '15563475-ed8-4b96-a99e-0fc2c90ed40a'	System	22 Oct 2020 18:06:40
User entered 'None (1)'	System	22 Oct 2020 18:06:40

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:30', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '15563475-ed8-4b96-a99e-0fc2c90ed40a'	System	22 Oct 2020 18:06:40
User entered 'No (N)'	System	22 Oct 2020 18:06:40

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:32', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '15563475-ed8-4b96-a99e-0fc2c90ed40a'	System	22 Oct 2020 18:06:40
User entered 'No (N)'	System	22 Oct 2020 18:06:40

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:34', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '15563475-ed8-4b96-a99e-0fc2c90ed40a'	System	22 Oct 2020 18:06:40
User entered 'None (1)'	System	22 Oct 2020 18:06:40

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:38', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '15563475-ed8-4b96-a99e-0fc2c90ed40a'	System	22 Oct 2020 18:06:40
User entered '22 Oct 2020 14:06'	System	22 Oct 2020 18:06:40

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:34', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'fc070be7-df65-464c-918e-3a2343a04118'	System	16 Oct 2020 15:11:53
User entered 'None (0)'	System	16 Oct 2020 15:11:53

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:36', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'fc070be7-df65-464c-918e-3a2343a04118'	System	16 Oct 2020 15:11:53
User entered 'None (0)'	System	16 Oct 2020 15:11:53

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:38', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'fc070be7-df65-464c-918e-3a2343a04118'	System	16 Oct 2020 15:11:53
User entered 'None (0)'	System	16 Oct 2020 15:11:53

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:41', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'fc070be7-df65-464c-918e-3a2343a04118'	System	16 Oct 2020 15:11:53
User entered 'None (0)'	System	16 Oct 2020 15:11:53

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:43', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'fc070be7-df65-464c-918e-3a2343a04118'	System	16 Oct 2020 15:11:53
User entered 'None (0)'	System	16 Oct 2020 15:11:53

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:45', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'fc070be7-df65-464c-918e-3a2343a04118'	System	16 Oct 2020 15:11:53
User entered 'None (0)'	System	16 Oct 2020 15:11:53

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:47', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'fc070be7-df65-464c-918e-3a2343a04118'	System	16 Oct 2020 15:11:53
User entered 'No (N)'	System	16 Oct 2020 15:11:53

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:50', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'fc070be7-df65-464c-918e-3a2343a04118'	System	16 Oct 2020 15:11:53
User entered '16 Oct 2020 11:11'	System	16 Oct 2020 15:11:53

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 10:56'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 13:26'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:34:53', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '74e4a625-a659-473a-ad65-b708187ca386'	System	16 Oct 2020 22:35:10
User entered 'None (0)'	System	16 Oct 2020 22:35:10

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:34:56', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '74e4a625-a659-473a-ad65-b708187ca386'	System	16 Oct 2020 22:35:10
User entered 'None (0)'	System	16 Oct 2020 22:35:10

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:34:57', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '74e4a625-a659-473a-ad65-b708187ca386'	System	16 Oct 2020 22:35:10
User entered 'None (0)'	System	16 Oct 2020 22:35:10

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:34:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '74e4a625-a659-473a-ad65-b708187ca386'	System	16 Oct 2020 22:35:10
User entered 'None (0)'	System	16 Oct 2020 22:35:10

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:35:01', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '74e4a625-a659-473a-ad65-b708187ca386'	System	16 Oct 2020 22:35:10
User entered 'None (0)'	System	16 Oct 2020 22:35:10

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:35:02', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '74e4a625-a659-473a-ad65-b708187ca386'	System	16 Oct 2020 22:35:10
User entered 'None (0)'	System	16 Oct 2020 22:35:10

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-16T18:35:04', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '74e4a625-a659-473a-ad65-b708187ca386'	System	16 Oct 2020 22:35:10
User entered 'No (N)'	System	16 Oct 2020 22:35:10

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:35:07', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '74e4a625-a659-473a-ad65-b708187ca386'	System	16 Oct 2020 22:35:10
User entered '16 Oct 2020 18:35'	System	16 Oct 2020 22:35:10

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 14:21'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 2'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:34', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cdb5ed74-21f0-4909-afd9-7a5baaef9ab0'	System	17 Oct 2020 19:42:00
User entered 'None (0)'	System	17 Oct 2020 19:42:00

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:40', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cdb5ed74-21f0-4909-afd9-7a5baaef9ab0'	System	17 Oct 2020 19:42:00
User entered 'No interference with activity (1)'	System	17 Oct 2020 19:42:00

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:42', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cdb5ed74-21f0-4909-afd9-7a5baaef9ab0'	System	17 Oct 2020 19:42:00
User entered 'None (0)'	System	17 Oct 2020 19:42:00

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:44', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cdb5ed74-21f0-4909-afd9-7a5baaef9ab0'	System	17 Oct 2020 19:42:00
User entered 'None (0)'	System	17 Oct 2020 19:42:00

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:46', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cdb5ed74-21f0-4909-afd9-7a5baaef9ab0'	System	17 Oct 2020 19:42:00
User entered 'None (0)'	System	17 Oct 2020 19:42:00

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:48', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cdb5ed74-21f0-4909-afd9-7a5baaef9ab0'	System	17 Oct 2020 19:42:00
User entered 'None (0)'	System	17 Oct 2020 19:42:00

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:51', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cdb5ed74-21f0-4909-afd9-7a5baaef9ab0'	System	17 Oct 2020 19:42:00
User entered 'No (N)'	System	17 Oct 2020 19:42:00

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cdb5ed74-21f0-4909-afd9-7a5baaef9ab0'	System	17 Oct 2020 19:42:00
User entered '17 Oct 2020 15:41'	System	17 Oct 2020 19:42:00

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 3'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:58', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bda2e95e-96e7-4746-99cd-e84c0ed3d4e1'	System	18 Oct 2020 18:15:13
User entered 'None (0)'	System	18 Oct 2020 18:15:13

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:15:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bda2e95e-96e7-4746-99cd-e84c0ed3d4e1'	System	18 Oct 2020 18:15:13
User entered 'None (0)'	System	18 Oct 2020 18:15:13

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:15:02', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bda2e95e-96e7-4746-99cd-e84c0ed3d4e1'	System	18 Oct 2020 18:15:13
User entered 'None (0)'	System	18 Oct 2020 18:15:13

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:15:04', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bda2e95e-96e7-4746-99cd-e84c0ed3d4e1'	System	18 Oct 2020 18:15:13
User entered 'None (0)'	System	18 Oct 2020 18:15:13

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:15:06', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bda2e95e-96e7-4746-99cd-e84c0ed3d4e1'	System	18 Oct 2020 18:15:13
User entered 'None (0)'	System	18 Oct 2020 18:15:13

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:15:07', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bda2e95e-96e7-4746-99cd-e84c0ed3d4e1'	System	18 Oct 2020 18:15:13
User entered 'None (0)'	System	18 Oct 2020 18:15:13

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-18T14:15:09', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bda2e95e-96e7-4746-99cd-e84c0ed3d4e1'	System	18 Oct 2020 18:15:13
User entered 'No (N)'	System	18 Oct 2020 18:15:13

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:15:12', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bda2e95e-96e7-4746-99cd-e84c0ed3d4e1'	System	18 Oct 2020 18:15:13
User entered '18 Oct 2020 14:15'	System	18 Oct 2020 18:15:13

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 4'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:18:04', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '95484fbc-1657-4cc1-a4db-8c395dcf7b9a'	System	19 Oct 2020 19:18:21
User entered 'No interference with activity (1)'	System	19 Oct 2020 19:18:21

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:18:06', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '95484fbc-1657-4cc1-a4db-8c395dcf7b9a'	System	19 Oct 2020 19:18:21
User entered 'None (0)'	System	19 Oct 2020 19:18:21

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:18:08', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '95484fbc-1657-4cc1-a4db-8c395dcf7b9a'	System	19 Oct 2020 19:18:21
User entered 'None (0)'	System	19 Oct 2020 19:18:21

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:18:09', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '95484fbc-1657-4cc1-a4db-8c395dcf7b9a'	System	19 Oct 2020 19:18:21
User entered 'None (0)'	System	19 Oct 2020 19:18:21

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:18:10', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '95484fbc-1657-4cc1-a4db-8c395dcf7b9a'	System	19 Oct 2020 19:18:21
User entered 'None (0)'	System	19 Oct 2020 19:18:21

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:18:12', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '95484fbc-1657-4cc1-a4db-8c395dcf7b9a'	System	19 Oct 2020 19:18:21
User entered 'None (0)'	System	19 Oct 2020 19:18:21

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-19T15:18:14', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '95484fbc-1657-4cc1-a4db-8c395dcf7b9a'	System	19 Oct 2020 19:18:21
User entered 'No (N)'	System	19 Oct 2020 19:18:21

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:18:16', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '95484fbc-1657-4cc1-a4db-8c395dcf7b9a'	System	19 Oct 2020 19:18:21
User entered '19 Oct 2020 15:18'	System	19 Oct 2020 19:18:21

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 5'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:20', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c8f4556a-2816-4fa0-a099-be65b6538b57'	System	20 Oct 2020 16:08:51
User entered 'None (0)'	System	20 Oct 2020 16:08:51

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:22', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c8f4556a-2816-4fa0-a099-be65b6538b57'	System	20 Oct 2020 16:08:51
User entered 'None (0)'	System	20 Oct 2020 16:08:51

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:24', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c8f4556a-2816-4fa0-a099-be65b6538b57'	System	20 Oct 2020 16:08:51
User entered 'None (0)'	System	20 Oct 2020 16:08:51

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:26', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c8f4556a-2816-4fa0-a099-be65b6538b57'	System	20 Oct 2020 16:08:51
User entered 'None (0)'	System	20 Oct 2020 16:08:51

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:28', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c8f4556a-2816-4fa0-a099-be65b6538b57'	System	20 Oct 2020 16:08:51
User entered 'None (0)'	System	20 Oct 2020 16:08:51

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:44', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c8f4556a-2816-4fa0-a099-be65b6538b57'	System	20 Oct 2020 16:08:51
User entered 'None (0)'	System	20 Oct 2020 16:08:51

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:46', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c8f4556a-2816-4fa0-a099-be65b6538b57'	System	20 Oct 2020 16:08:51
User entered 'No (N)'	System	20 Oct 2020 16:08:51

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:49', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c8f4556a-2816-4fa0-a099-be65b6538b57'	System	20 Oct 2020 16:08:51
User entered '20 Oct 2020 12:08'	System	20 Oct 2020 16:08:51

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 6'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:03:07', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9632983a-d7c0-4130-89d8-06e89b76d691'	System	21 Oct 2020 18:03:25
User entered 'No interference with activity (1)'	System	21 Oct 2020 18:03:25

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:03:08', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9632983a-d7c0-4130-89d8-06e89b76d691'	System	21 Oct 2020 18:03:25
User entered 'None (0)'	System	21 Oct 2020 18:03:25

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:03:10', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9632983a-d7c0-4130-89d8-06e89b76d691'	System	21 Oct 2020 18:03:25
User entered 'None (0)'	System	21 Oct 2020 18:03:25

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:03:12', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9632983a-d7c0-4130-89d8-06e89b76d691'	System	21 Oct 2020 18:03:25
User entered 'None (0)'	System	21 Oct 2020 18:03:25

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:03:13', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9632983a-d7c0-4130-89d8-06e89b76d691'	System	21 Oct 2020 18:03:25
User entered 'None (0)'	System	21 Oct 2020 18:03:25

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:03:14', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9632983a-d7c0-4130-89d8-06e89b76d691'	System	21 Oct 2020 18:03:25
User entered 'None (0)'	System	21 Oct 2020 18:03:25

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-21T14:03:16', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9632983a-d7c0-4130-89d8-06e89b76d691'	System	21 Oct 2020 18:03:25
User entered 'No (N)'	System	21 Oct 2020 18:03:25

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:03:19', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9632983a-d7c0-4130-89d8-06e89b76d691'	System	21 Oct 2020 18:03:25
User entered '21 Oct 2020 14:03'	System	21 Oct 2020 18:03:25

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 7'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:42', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '840569c7-6906-4e37-ad18-5567d24fd5f2'	System	22 Oct 2020 18:06:55
User entered 'None (0)'	System	22 Oct 2020 18:06:55

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:43', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '840569c7-6906-4e37-ad18-5567d24fd5f2'	System	22 Oct 2020 18:06:55
User entered 'None (0)'	System	22 Oct 2020 18:06:55

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:45', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '840569c7-6906-4e37-ad18-5567d24fd5f2'	System	22 Oct 2020 18:06:55
User entered 'None (0)'	System	22 Oct 2020 18:06:55

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:47', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '840569c7-6906-4e37-ad18-5567d24fd5f2'	System	22 Oct 2020 18:06:55
User entered 'None (0)'	System	22 Oct 2020 18:06:55

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:48', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '840569c7-6906-4e37-ad18-5567d24fd5f2'	System	22 Oct 2020 18:06:55
User entered 'None (0)'	System	22 Oct 2020 18:06:55

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:50', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '840569c7-6906-4e37-ad18-5567d24fd5f2'	System	22 Oct 2020 18:06:55
User entered 'None (0)'	System	22 Oct 2020 18:06:55

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

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 (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:51', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '840569c7-6906-4e37-ad18-5567d24fd5f2'	System	22 Oct 2020 18:06:55
User entered 'No (N)'	System	22 Oct 2020 18:06:55

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:54', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '840569c7-6906-4e37-ad18-5567d24fd5f2'	System	22 Oct 2020 18:06:55
User entered '22 Oct 2020 14:06'	System	22 Oct 2020 18:06:55

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 04:58:16

US3602030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '23 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 04:58:16

US3602030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Oct 2020 04:58:16

US3602030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:58:16

US3602030

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 04:58:21

US3602030

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 04:58:21

US3602030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 16:29:59

US3602030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Nov 2020 16:30:11
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	09 Nov 2020 16:30:11
User entered '30 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 16:30:11
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Nov 2020 16:29:59
User entered '16 Oct 2020'	(b) (4), (b) (6)	09 Nov 2020 16:29:59

US3602030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Nov 2020 16:29:59

US3602030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:29:59

US3602030

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 16:30:18

US3602030

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 16:30:18

US3602030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 16:30:37

US3602030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '6 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 16:30:37

US3602030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Nov 2020 16:30:37

US3602030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:30:37

US3602030

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 16:30:44

US3602030

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 16:30:44

US3602030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 15:17:44

US3602030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '13 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 15:17:44

US3602030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	18 Nov 2020 15:17:44

US3602030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	18 Nov 2020 15:17:44

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '09:25'	(b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '13 Nov 2020 09:25'	System	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.4' F	(b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Temporal'	(b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '83'	(b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '122'	(b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 15:19:09

US3602030

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 15:19:09

US3602030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 15:19:37

US3602030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 15:19:37

US3602030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:25'	(b) (4), (b) (6)	18 Nov 2020 15:19:37

US3602030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '13 Nov 2020 09:25'	System	18 Nov 2020 15:19:37

US3602030

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 15:19:41

US3602030

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 15:19:41

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 71'	System	11 Sep 2020 16:00:13

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

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 (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-11-19T09:35:23', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4e24a4a7-ef73-4383-b511-05396d217372'	System	19 Nov 2020 14:35:43
User entered 'No (N)'	System	19 Nov 2020 14:35:43

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

Have you been exposed to someone with 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 (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-11-19T09:35:32', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4e24a4a7-ef73-4383-b511-05396d217372'	System	19 Nov 2020 14:35:43
User entered 'No (N)'	System	19 Nov 2020 14:35:43

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-11-19T09:35:40', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4e24a4a7-ef73-4383-b511-05396d217372'	System	19 Nov 2020 14:35:43
User entered '19 Nov 2020 09:35:40'	System	19 Nov 2020 14:35:43

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 16:00:13

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 16:00:13
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '08 Nov 2020 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '12 Nov 2020 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '15 Nov 2020 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '19 Nov 2020 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[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 (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-11-22T09:16:21', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '23cb8628-1a08-4a02-bac1-da37801ea20f'	System	22 Nov 2020 14:16:32
User entered 'No (N)'	System	22 Nov 2020 14:16:32

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

Have you been exposed to someone with 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 (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-11-22T09:16:26', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '23cb8628-1a08-4a02-bac1-da37801ea20f'	System	22 Nov 2020 14:16:32
User entered 'No (N)'	System	22 Nov 2020 14:16:32

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-11-22T09:16:29', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '23cb8628-1a08-4a02-bac1-da37801ea20f' User entered '22 Nov 2020 09:16:29'	System	22 Nov 2020 14:16:32
	System	22 Nov 2020 14:16:32

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:08:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:08:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:08:32

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:08:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:08:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:08:32

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:08:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:08:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:08:32

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:08:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:08:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:08:32

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:08:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:08:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:08:32

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:08:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:08:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:08:32

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:08:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:08:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:08:32

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:38:09

US3602030

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 04:36:13

US3602030

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	28 Oct 2020 04:36:13

US3602030

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Oct 2020 04:36:13

US3602030

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	28 Oct 2020 04:36:13

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 04:37:16

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	28 Oct 2020 04:37:16

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '8:52'	(b) (4), (b) (6)	28 Oct 2020 04:37:16

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '22 Sep 2020 8:52'	System	28 Oct 2020 04:37:16

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Oct 2020 04:37:16
DataPoint set to visible.	System	28 Oct 2020 04:36:13

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

Weight (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Oct 2020 04:37:16
DataPoint set to visible.	System	28 Oct 2020 04:36:13

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 06:12:45
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	(b) (4), (b) (6)	28 Oct 2020 04:37:32
answered with 'NCS per provider' (Site from System).		
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Oct 2020 04:37:16
User entered '96.4' F	(b) (4), (b) (6)	28 Oct 2020 04:37:16

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	28 Oct 2020 04:37:16

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'unknown'	(b) (4), (b) (6)	28 Oct 2020 04:37:16

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '98'	(b) (4), (b) (6)	28 Oct 2020 04:37:16

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Oct 2020 04:37:16

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '12'	(b) (4), (b) (6)	28 Oct 2020 04:37:16

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Oct 2020 04:37:16

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '121'	(b) (4), (b) (6)	28 Oct 2020 04:37:16

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Oct 2020 04:37:16

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '81'	(b) (4), (b) (6)	28 Oct 2020 04:37:16

US3602030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Oct 2020 04:37:16

US3602030

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 04:37:41

US3602030

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	28 Oct 2020 04:37:41

US3602030

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:08:32

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	28 Oct 2020 04:38:17
reason for change: Data Entry Error		
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 04:37:50

US3602030

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:08:32

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:37:50

US3602030

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 15:43:41

US3602030

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 15:43:41

US3602030

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 15:43:41

US3602030

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:32

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	18 Nov 2020 15:43:41

US3602030

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:08:32

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:20:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 13:48:41

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:38:48
User entered 'USA-US079-2020-mRNA-1273-P301000001'	System	23 Sep 2020 11:38:43
User entered 'New'	(b) (4), (b) (6)	23 Sep 2020 11:38:43

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Swelling face, LLT: Swelling of face - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 21:25:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	09 Oct 2020 21:25:32
Data point term sent to Coder	System	09 Oct 2020 19:21:42
User closed query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate records, e.g. SWELLING FACE / TINGLING with location / NUMBENESS with location' (Site from System).	System	09 Oct 2020 19:21:37
Query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate records, e.g. SWELLING FACE / TINGLING with location / NUMBENESS with location' answered with 'will update' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 19:21:37
Data point term sent to Coder	System	09 Oct 2020 19:10:17
User entered 'SWELLING TO THE RIGHT SIDE OF THE FACE' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:09:23
User opened query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate records, e.g. SWELLING FACE / TINGLING with location / NUMBENESS with location' (Site from System).	Coder Import (b) (4)	08 Oct 2020 11:02:18
Data point term sent to Coder	System	22 Sep 2020 14:13:08
User entered 'Swelling to the right side of the face and tingling numbness'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered '17 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Sep 2020 14:46:22
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 14:46:22
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Sep 2020 14:12:38
User entered '16:00'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 14:46:22
User entered '17 Sep 2020 16:00'	System	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 19:24:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered '27 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 19:24:15
Query 'PV query: Please provide the stop date for the event of swelling to the right side of the face and tingling numbness, when available. Please do not respond to this query until the event has ended.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 12:49:59
User opened query 'PV query: Please provide the stop date for the event of swelling to the right side of the face and tingling numbness, when available. Please do not respond to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		22 Sep 2020 14:46:35
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		22 Sep 2020 14:46:35
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	22 Sep 2020 14:12:38
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

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Folder: Adverse Events

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[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 14:46:35
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:12:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

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Folder: Adverse Events

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Generated On: 26 Nov 2020 11:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered 'Related (RELATED)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
Query 'PV query: Please confirm if the study drug was withdrawn in response to the events. If so, please update the action taken.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 12:50:03
User opened query 'PV query: Please confirm if the study drug was withdrawn in response to the events. If so, please update the action taken.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:36:29
User entered 'None (NONE)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[None](#)

Audit	User	Time (GMT)
User entered '0' reason for change: New Information	(b) (4), (b) (6)	18 Nov 2020 15:56:38
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 15:37:34
User entered '1' reason for change: New Information	(b) (4), (b) (6)	18 Nov 2020 15:37:34
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please consider updating the Concomitant Procedure page with this AE or clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:46:02
Query 'Per CDM: Please consider updating the Concomitant Procedure page with this AE or clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:23:22
User closed query 'Per DM CLR: RQ: Response noted, however, there were no updates provided. Please make sure a therapeutic procedure is recorded for this AE or update response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:53:54
User opened query 'Per CDM: Please consider updating the Concomitant Procedure page with this AE or clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:53:51
User entered '1' reason for change: New Information	(b) (4), (b) (6)	18 Nov 2020 15:56:38
Query 'Per DM CLR: RQ: Response noted, however, there were no updates provided. Please make sure a therapeutic procedure is recorded for this AE or update response as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:37:50
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 15:37:34
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Nov 2020 15:37:34
User opened query 'Per DM CLR: RQ: Response noted, however, there were no updates provided. Please make sure a therapeutic procedure is recorded for this AE or update response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 12:10:31
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:49:40

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 13:24:13
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 09:28:01
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 19:24:15
Query 'PV query: Please provide the final outcome for the event of swelling to the right side of the face and tingling numbness, when available. Please do not respond to this query until the event has ended.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 12:50:06
User opened query 'PV query: Please provide the final outcome for the event of swelling to the right side of the face and tingling numbness, when available. Please do not respond to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:34:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:12:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User closed query 'PV query: Please consider adding sinus surgery to the medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 20:26:13
Query 'PV query: Please consider adding sinus surgery to the medical history eCRF.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 16:34:49
User opened query 'PV query: Please consider adding sinus surgery to the medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:48:22
User closed query 'Per DM CLR: SAE Narrative = HAD HER TOOTH CLEANING AND ROOT CANAL DONE AUG 6TH AND AUGUST 28TH and PMHX OF SINUS SURGERIES IN THE PAST. However, these information were not recorded in the Med History eCRF. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:53:13
Query 'Per DM CLR: SAE Narrative = HAD HER TOOTH CLEANING AND ROOT CANAL DONE AUG 6TH AND AUGUST 28TH and PMHX OF SINUS SURGERIES IN THE PAST. However, these information were not recorded in the Med History eCRF. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 13:21:34
User opened query 'Per DM CLR: SAE Narrative = HAD HER TOOTH CLEANING AND ROOT CANAL DONE AUG 6TH AND AUGUST 28TH and PMHX OF SINUS SURGERIES IN THE PAST. However, these information were not recorded in the Med History eCRF. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 09:28:10
Query 'PV query: Please confirm if the subject went to ENT and what their diagnosis was.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 12:50:14
Query 'PV query: Please consider adding sinus surgery to the medical history eCRF.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 12:50:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:32

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please confirm if the subject went to ENT and what their diagnosis was.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:35:59
User opened query 'PV query: Please consider adding sinus surgery to the medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:35:36
User entered 'pt had Her IP on sep 11th Had her tooth cleaning and root canal done Aug 6th and august 28th and was well prior to the vaccine PMHx of sinus surgeries in the past No issues related tot he vaccine itself but then on Thursday started with pain on chewing in the back teeth and thought was related to the root canal and never mentioned it on the safety call with me on Friday the 18th Over the next 24hr had increasing tingling and numbness along the jaw line and increasing swelling and fullness over the maxilla No nasal discharge The pain persisted on the weekend and she saw her dentist on 9/21 and called me from there since The dentist did not find any issues with the tooth and felt that it could be shingles and of some other medical issues leading to referred pain On today's limited exam: Vitals : 96.4 , 128/81, plse ox 100% HR 98 rr 12 BMI 38.4 she does have swelling to the cheek and jaw area No redness to the face No tooth decay noted , no pain on palpation of the tooth No swelling of the jaw No facial droop No nasal congestion or redness rec : seek eval by ENT and or medical doctor Have the dentist and the other physicians she sees to fax the records to us (b) (6)	(b) (4), (b) (6)	22 Sep 2020 14:12:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 14:12:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 14:12:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Sep 2020 14:12:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:13
User entered 'USA-US079-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	23 Sep 2020 11:39:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Vaccination related complications, PT: Immunisation anxiety related reaction, LLT: Immunization anxiety related reaction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:20:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:20:21
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:06:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:06:41
Data point term sent to Coder	System	22 Sep 2020 14:38:47
User entered 'Anxiety Related to the Vaccine'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

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Folder: Adverse Events

Form: Adverse Events (2)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 14:44:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 14:44:14
User entered '17 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 14:44:14
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 14:38:21
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Sep 2020 14:46:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 14:46:01
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Sep 2020 14:44:14
User entered '16:00' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 14:44:14
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 14:46:01
User entered '17 Sep 2020 16:00'	System	22 Sep 2020 14:44:14
User entered empty.	System	22 Sep 2020 14:38:21

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	09 Oct 2020 19:26:10
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 19:26:10
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	09 Oct 2020 19:25:27
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 14:44:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 14:44:14
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 14:44:14
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 14:38:21
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User closed query 'PV query: Please provide the stop date for the event of anxiety related to the vaccine., when available. Please do not respond to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 12:53:28
Query 'PV query: Please provide the stop date for the event of anxiety related to the vaccine., when available. Please do not respond to this query until the event has ended.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 19:25:38
User entered '7 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 19:25:27
User opened query 'PV query: Please provide the stop date for the event of anxiety related to the vaccine., when available. Please do not respond to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:37:21
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

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Folder: Adverse Events

Form: Adverse Events (2)

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

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Form: Adverse Events (2)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 14:38:21

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

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Folder: Adverse Events

Form: Adverse Events (2)

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[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered 'Related (RELATED)'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User closed query 'PV query: Please confirm if the study drug was withdrawn in response to the events. If so, please update the action taken.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 12:53:33
Query 'PV query: Please confirm if the study drug was withdrawn in response to the events. If so, please update the action taken.' answered with 'drug was not withdrawn' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 19:25:13
User opened query 'PV query: Please confirm if the study drug was withdrawn in response to the events. If so, please update the action taken.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:37:38
User entered 'None (NONE)'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[None](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 15:38:17
User entered '1' reason for change: New Information	(b) (4), (b) (6)	18 Nov 2020 15:38:17
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: RQ: Response noted, however, please confirm any therapeutic procedure/s was done during the visit and add those in the Con Proc eCRF. Otherwise, update the response as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:54:59
Query 'Per DM CLR: RQ: Response noted, however, please confirm any therapeutic procedure/s was done during the visit and add those in the Con Proc eCRF. Otherwise, update the response as appropriate.'	(b) (4), (b) (6)	18 Nov 2020 15:38:27
answered with 'updated' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 15:38:17
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Nov 2020 15:38:17
User opened query 'Per DM CLR: RQ: Response noted, however, please confirm any therapeutic procedure/s was done during the visit and add those in the Con Proc eCRF. Otherwise, update the response as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 12:12:20
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User closed query 'Per CDM: Concomitant Procedure checkbox is selected However, no any procedure recorded related to this eve. Please uncheck the box or else review and clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:38:43
Query 'Per CDM: Concomitant Procedure checkbox is selected However, no any procedure recorded related to this eve. Please uncheck the box or else review and clarify. Thank you.' answered with 'patient was seen for an illness visit.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:39:22
User opened query 'Per CDM: Concomitant Procedure checkbox is selected However, no any procedure recorded related to this eve. Please uncheck the box or else review and clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:05:51

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:57:03
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.	(b) (4), (b) (6)	15 Oct 2020 13:24:24
' answered with 'updated' (Site from DM).		
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.	(b) (4), (b) (6)	15 Oct 2020 09:25:45
' (Site from DM).		
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User closed query 'PV query: Please provide the final outcome for the event of anxiety related to the vaccine, when available. Please do not respond to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 12:53:37
Query 'PV query: Please provide the final outcome for the event of anxiety related to the vaccine, when available. Please do not respond to this query until the event has ended.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 19:25:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:25:27
User opened query 'PV query: Please provide the final outcome for the event of anxiety related to the vaccine, when available. Please do not respond to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:37:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Sep 2020 14:44:14
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	22 Sep 2020 14:44:14
User entered 'No issues related tot he vaccine itself but then on Thursday started with pain on chewing in the back teeth and thought was related to the root canal and never mentioned it on the safety call with me on Friday the 18th On today's limited exam: Vitals : 96.4 , 128/81, plse ox 100% HR 98 rr 12 BMI 38.4 she does have swelling to the cheek and jaw area No redness to the face No tooth decay noted , no pain on palpation of the tooth No swelling of the jaw No facial droop No nasal congestion or redness' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 14:44:14
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Sep 2020 14:38:21
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:28:03
User entered 'USA-US079-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	12 Oct 2020 12:27:49

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Paraesthesia, LLT: Facial paraesthesia - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 20:08:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 20:08:33
Data point term sent to Coder	System	09 Oct 2020 19:13:22
User entered 'Tingling on Right Side of Face'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '17 Sep 2020'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	09 Oct 2020 19:13:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:13:16
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	09 Oct 2020 19:12:42
User entered '4:00'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:13:16
User entered '17 Sep 2020 4:00'	System	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Oct 2020 19:19:18
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	09 Oct 2020 19:19:18
User entered '28 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:19:18
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Oct 2020 19:17:29
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	09 Oct 2020 19:17:29
User entered '7 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:17:29
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	09 Oct 2020 19:12:42
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:12:42

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:12:42

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Folder: Adverse Events

Form: Adverse Events (3)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	09 Oct 2020 19:13:16
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	09 Oct 2020 19:12:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:12:42

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:13:16
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered 'Related (RELATED)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered 'None (NONE)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

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Folder: Adverse Events

Form: Adverse Events (3)

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '1'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:19:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:12:42

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:08
User closed query 'PV query: Please consider adding sinus surgery to the medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:44:08
User closed query 'PV query: Please confirm if the subject went to ENT and what their diagnosis was.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:41:06
Query 'PV query: Please consider adding sinus surgery to the medical history eCRF.' answered with 'will update' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:41:05
Query 'PV query: Please confirm if the subject went to ENT and what their diagnosis was.' answered with 'ENT feels the tingling is odontogenic' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:41:00
User opened query 'PV query: Please consider adding sinus surgery to the medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:30:38
User opened query 'PV query: Please confirm if the subject went to ENT and what their diagnosis was.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[Narrative](#)

Audit	User	Time (GMT)
User entered 'pt had Her IP on sep 11th Had her tooth cleaning and root canal done Aug 6th and august 28th and was well prior to the vaccine PMHx of sinus surgeries in the past No issues related tot he vaccine itself but then on Thursday started with pain on chewing in the back teeth and thought was related to the root canal and never mentioned it on the safety call with me on Friday the 18th Over the next 24hr had increasing tingling and numbness along the jaw line and increasing swelling and fullness over the maxilla No nasal discharge The pain persisted on the weekend and she saw her dentist on 9/21 and called me from there since The dentist did not find any issues with the tooth and felt that it could be shingles and of some other medical issues leading to referred pain On today's limited exam: Vitals : 96.4 , 128/81, plse ox 100% HR 98 rr 12 BMI 38.4 she does have swelling to the cheek and jaw area No redness to the face No tooth decay noted , no pain on palpation of the tooth No swelling of the jaw No facial droop No nasal congestion or redness rec : seek eval by ENT and or medical doctor Have the dentist and the other physicians she sees to fax the records to us (b) (6)	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:08:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:28:43
User entered 'USA-US079-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	12 Oct 2020 12:28:38

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' canceled (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:56:16
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Lower respiratory tract signs and symptoms, PT: Pleuritic pain, LLT: Pleuritic pain - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 21:05:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	09 Oct 2020 21:05:49
Data point term sent to Coder	System	09 Oct 2020 19:28:58
User entered 'Left sided Pleuritic chest pain'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '27 Sep 2020'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '29 Sep 2020'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '1'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User closed query 'Per CDM: Per CCG pg.33, 'Not applicable' should be use if clinical event is prior to first dose/investigational product. Please consider to update appropriately or else, clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:30:56
Query 'Per CDM: Per CCG pg.33, 'Not applicable' should be use if clinical event is prior to first dose/investigational product. Please consider to update appropriately or else, clarify. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:28:14
User entered 'Not Related (NOT RELATED)' reason for change: New Information	(b) (4), (b) (6)	29 Oct 2020 21:28:06
User opened query 'Per CDM: Per CCG pg.33, 'Not applicable' should be use if clinical event is prior to first dose/investigational product. Please consider to update appropriately or else, clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 10:57:52
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User closed query 'Per CDM: Per CCG pg.33, 'Not applicable' should be use if clinical event is prior to first dose/investigational product. Please consider to update appropriately or else, clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:30:59
Query 'Per CDM: Per CCG pg.33, 'Not applicable' should be use if clinical event is prior to first dose/investigational product. Please consider to update appropriately or else, clarify. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:28:19
User entered 'Not Related (NOT RELATED)' reason for change: New Information	(b) (4), (b) (6)	29 Oct 2020 21:28:06
User opened query 'Per CDM: Per CCG pg.33, 'Not applicable' should be use if clinical event is prior to first dose/investigational product. Please consider to update appropriately or else, clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 10:58:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered 'None (NONE)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '1'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results for the event of pleuritic chest pain. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:45:40
User closed query 'PV query: It was reported that stress test and echo were planned for Oct 13. Please provide the results.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:45:34
User closed query 'PV Query: Please provide treatment given for the event of pleuritic chest pain, including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:45:10
Query 'PV Query: Please provide treatment given for the event of pleuritic chest pain, including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'no additional medications or treatment. subject should continue q6o FU with Cardiologist' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:48:31
Query 'PV query: It was reported that stress test and echo were planned for Oct 13. Please provide the results.' answered with 'regular stress test no ischemia, ehco shows: Left ventricle cavity is normal in size. Normal global wall motion. Visual EF is 55-60%. Doppler evidence of grade I (impaired) diastolic dysfunction. Structurally normal trileaflet aortic valve with mild (Grade I) Regurgitation.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:47:32

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results for the event of pleuritic chest pain. Please include units and reference ranges if applicable.' answered with 'states "all tests were negative" do not have physical lab result' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:44:28
User opened query 'PV Query: Please provide treatment given for the event of pleuritic chest pain, including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:27:24
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results for the event of pleuritic chest pain. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:27:07
User opened query 'PV query: It was reported that stress test and echo were planned for Oct 13. Please provide the results.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:26:48
User entered 'L sided back / thoracic chest pain so she went to her PCP on 9/28 and had an ekG done which was normal . SHe had labs done today (nl) and Had a CXR done which was also normal . . No meds and no OTC take thus far . Was sent to the cardiologist (b) (6) , whom she saw today 10/7 and had evaluation Done . He did not think it is cardiac in origin but rec echo (10/9) and stress test on (10/13)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:08:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:29:22
User entered 'USA-US079-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	12 Oct 2020 12:29:17

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:54:19
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'no subject followed up with cardiologist' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:46:41
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:59:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Feeling hot, LLT: Localised feeling of warmth - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:05:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:05:49
Data point term sent to Coder	System	09 Oct 2020 19:31:00
User entered 'Left sided chest wall warmth'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 19:30:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 19:30:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:30:38
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 19:30:23
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered '6 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	28 Oct 2020 04:53:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User closed query 'PV query: Please provide the stop date of left sided chest wall warmth, when available. Please do not response to the query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:48:20
Query 'PV query: Please provide the stop date of left sided chest wall warmth, when available. Please do not response to the query until the event has ended.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:54:02
User entered '16 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	28 Oct 2020 04:53:55
User opened query 'PV query: Please provide the stop date of left sided chest wall warmth, when available. Please do not response to the query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:23:18
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered '1'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered 'Related (RELATED)'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered 'Related (RELATED)'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User closed query 'Per CDM: Action Taken with Investigational Product is Withdrawn, however Dosing Discontinuation is not completed. Please consider to complete all applicable forms. Thank you' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 03:32:47
Query 'Per CDM: Action Taken with Investigational Product is Withdrawn, however Dosing Discontinuation is not completed. Please consider to complete all applicable forms. Thank you' answered with 'updated to correct action' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:54:10
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: New Information	(b) (4), (b) (6)	28 Oct 2020 04:53:55
User opened query 'Per CDM: Action Taken with Investigational Product is Withdrawn, however Dosing Discontinuation is not completed. Please consider to complete all applicable forms. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 11:04:54
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: RQ: Response noted, however, please confirm any therapeutic procedure/s was done during the visit and add those in the Con Proc eCRF. Otherwise, update the response as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 19:16:46
Query 'Per DM CLR: RQ: Response noted, however, please confirm any therapeutic procedure/s was done during the visit and add those in the Con Proc eCRF. Otherwise, update the response as appropriate.'	(b) (4), (b) (6)	18 Nov 2020 15:38:53
answered with 'updated' (Site from DM).		
User opened query 'Per DM CLR: RQ: Response noted, however, please confirm any therapeutic procedure/s was done during the visit and add those in the Con Proc eCRF. Otherwise, update the response as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User closed query 'Per CDM: Concomitant Procedure checkbox is selected However, no any procedure recorded related to this event. Please confirm and update or else clarify. Thank you. (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:39:28
Query 'Per CDM: Concomitant Procedure checkbox is selected However, no any procedure recorded related to this event. Please confirm and update or else clarify. Thank you. answered with 'subject was seen by other medical professionals' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:54:28
User opened query 'Per CDM: Concomitant Procedure checkbox is selected However, no any procedure recorded related to this event. Please confirm and update or else clarify. Thank you. (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:09:26
Query ' Per CDM: Concomitant medication checkbox is selected However, no any medication recorded related to this event. Please confirm and update the medication on Concomitant medication form if it is given or else clarify. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:07:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query ' Per CDM: Concomitant medication checkbox is selected However, no any medication recorded related to this event. Please confirm and update the medication on Concomitant medication form if it is given or else clarify. Thank you. ' (Site from DM). User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 11:06:09
	(b) (4), (b) (6) (b) (4), (b) (6)	09 Oct 2020 19:30:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User closed query 'PV query: Please provide the final outcome of left sided chest wall warmth, when available. Please do not response to the query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:49:09
Query 'PV query: Please provide the final outcome of left sided chest wall warmth, when available. Please do not response to the query until the event has ended.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:54:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	28 Oct 2020 04:53:55
User opened query 'PV query: Please provide the final outcome of left sided chest wall warmth, when available. Please do not response to the query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:23:00
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered 'Will Not be pursuing the second Dose of the investigational product Started with chest wall pain and tingling and feeling of warmth to the side that started yesterday evening while lying down And mentioned it to the cardiologist too . SHe has been recommended to have the neurologist assess her for any etiology for the symptoms Pt is going to be making an appt and will let us know the outcome	(b) (4), (b) (6)	09 Oct 2020 19:30:23

She does ask me to un blind her from the study given various symptoms with no diagnosis made and concern for vaccine related issues

I have had the discussion with (b) (6) reg the same'

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:08:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:30:38

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:29:56
User entered 'USA-US079-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	12 Oct 2020 12:29:51

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' canceled (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:56:05
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:59:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Paraesthesia, LLT: Localized tingling - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 21:10:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	09 Oct 2020 21:10:33
Data point term sent to Coder	System	09 Oct 2020 19:43:21
User entered 'Left Sided Tingling'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered '6 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:42:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	28 Oct 2020 04:53:13
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	28 Oct 2020 04:53:13
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	28 Oct 2020 04:52:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User closed query 'PV query: Please provide the stop date of left sided tingling, when available. Please do not response to the query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:46:56
Query 'PV query: Please provide the stop date of left sided tingling, when available. Please do not response to the query until the event has ended.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:53:04
User entered '16 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	28 Oct 2020 04:52:14
User opened query 'PV query: Please provide the stop date of left sided tingling, when available. Please do not response to the query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:25:09
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:42:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:42:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered '1'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered '1'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered 'Related (RELATED)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered 'Related (RELATED)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User closed query 'Per CDM: Action Taken with Investigational Product is Withdrawn, however Dosing Discontinuation page is not completed. Please consider to complete all applicable forms. Thank you' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 03:34:38
Query 'Per CDM: Action Taken with Investigational Product is Withdrawn, however Dosing Discontinuation page is not completed. Please consider to complete all applicable forms. Thank you' answered with 'updated to correct action' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:52:50
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 04:52:14
User opened query 'Per CDM: Action Taken with Investigational Product is Withdrawn, however Dosing Discontinuation page is not completed. Please consider to complete all applicable forms. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 11:07:40
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: RQ: Response noted, however, please confirm any therapeutic procedure/s was done during the visit and add those in the Con Proc eCRF. Otherwise, update the response as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 19:17:05
Query 'Per DM CLR: RQ: Response noted, however, please confirm any therapeutic procedure/s was done during the visit and add those in the Con Proc eCRF. Otherwise, update the response as appropriate.'	(b) (4), (b) (6)	18 Nov 2020 15:39:01
answered with 'updated' (Site from DM).		
User opened query 'Per DM CLR: RQ: Response noted, however, please confirm any therapeutic procedure/s was done during the visit and add those in the Con Proc eCRF. Otherwise, update the response as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 12:12:59
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User closed query 'Per CDM: Concomitant Procedure checkbox is selected However, no any procedure recorded related to this event. Please review and update or else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:40:02
Query 'Per CDM: Concomitant Procedure checkbox is selected However, no any procedure recorded related to this event. Please review and update or else clarify. Thank you' answered with 'Patient was seen by other medical professionals.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:51:50
User opened query 'Per CDM: Concomitant Procedure checkbox is selected However, no any procedure recorded related to this event. Please review and update or else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:11:00
Query 'Per CDM: Concomitant medication checkbox is selected However, no any medication recorded related to this event. Please confirm and update the medication on Concomitant medication form if it is given or else clarify. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:10:34

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Concomitant medication checkbox is selected However, no any medication recorded related to this event. Please confirm and update the medication on Concomitant medication form if it is given or else clarify. Thank you. ' (Site from DM). User entered '1'	(b) (4), (b) (6)	16 Oct 2020 11:08:34
	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User closed query 'PV query: PV query: Please provide the final outcome of left sided tingling, when available. Please do not response to the query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:47:07
Query 'PV query: PV query: Please provide the final outcome of left sided tingling, when available. Please do not response to the query until the event has ended.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:52:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	28 Oct 2020 04:52:14
User opened query 'PV query: PV query: Please provide the final outcome of left sided tingling, when available. Please do not response to the query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:24:56
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User closed query 'PV Query: Please provide the of the neurology consult for pain, warmth and tingling of the left side of the chest wall.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:46:42
Query 'PV Query: Please provide the of the neurology consult for pain, warmth and tingling of the left side of the chest wall.' answered with 'Subject has not seen neurology as of yet' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:52:31
User opened query 'PV Query: Please provide the of the neurology consult for pain, warmth and tingling of the left side of the chest wall.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:24:44
User entered 'Started with chest wall pain and tingling and feeling of warmth to the side that started yesterday evening while lying down And mentioned it to the cardiologist too . SHe has been recommended to have the neurologist assess her for any etiology for the symptoms Pt is going to be making an appt and will let us know the outcome	(b) (4), (b) (6)	09 Oct 2020 19:42:33

She does ask me to un blind her from the study given various symptoms with no diagnosis made and concern for vaccine related issues

I have had the discussion with (b) (6) reg the same'

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:08:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' canceled (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:56:30
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:59:57
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Oct 2020 06:28:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Oct 2020 06:28:11
Data point term sent to Coder	System	28 Oct 2020 04:56:55
User entered 'Headache'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '18 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '24 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[None](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:08:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:25:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:25:35
Data point term sent to Coder	System	11 Nov 2020 20:09:30
User entered 'Migraine Headache'	(b) (4), (b) (6) (b) (4)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '04 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:08:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:11:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:11:37
Data point term sent to Coder	System	11 Nov 2020 20:10:37
User entered 'Migraine Headache'	(b) (4), (b) (6) (b) (4)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '02 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '03 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:08:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 20:09:37

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:08:32

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:20:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:11:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: ETONOGESTREL, PRODUCTSYNONYM: NEXPLANON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 16:16:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 16:16:40
Data point term sent to Coder	System	11 Sep 2020 16:15:50
User entered 'Nexplanon'	(b) (4), (b) (6) (b) (4)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User entered 'Contraception and Endometriosis'	(b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User entered 'n/a'	(b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'n/a'	(b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	(b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'q 3years'	(b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 16:15:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 16:15:31
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 16:15:31
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 16:14:55
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered 'Intradermal' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 16:15:31
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '24 Jun 2020'	(b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 18:21:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 18:21:45
Data point term sent to Coder	System	21 Oct 2020 18:20:30
Coding entries removed.	(b) (4), (b) (6)	21 Oct 2020 18:19:43
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 16:17:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 16:17:37
Data point term sent to Coder	System	11 Sep 2020 16:16:58
User entered 'Advair'	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User entered 'Asthma' reason for change: New Information	(b) (4), (b) (6)	21 Oct 2020 18:19:43
User entered 'Rhinitis'	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '250/50'	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:02:16
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:29:51
User entered 'Other (OTHER)' reason for change: New Information	(b) (4), (b) (6)	29 Oct 2020 21:29:47
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:07:12
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'mcg' reason for change: New Information	(b) (4), (b) (6)	29 Oct 2020 21:29:47
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'UN UNK 2004'	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: TELMISARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 16:18:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 16:18:39
Data point term sent to Coder	System	11 Sep 2020 16:18:03
User entered 'Telmisartan'	(b) (4), (b) (6) (b) (4)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User entered 'HTN'	(b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	(b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	(b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: CICLOSPORIN, PRODUCTSYNONYM: RESTASIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 04:39:51
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 Nov 2020 04:39:51
Data point term sent to Coder	System	29 Oct 2020 21:31:44
Coding entries removed.	(b) (4), (b) (6)	29 Oct 2020 21:30:43
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: CICLOSPORIN, PRODUCTSYNONYM: RESTASIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 08:10:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 08:10:46
Data point term sent to Coder	System	11 Sep 2020 16:20:15
User entered 'Restasis 0.5 mg/ml'	(b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User entered 'Dry Eye'	(b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2'	(b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'gtts'	(b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Other: Ophthalmic). Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:02:32
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Other: Ophthalmic). Please update route as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:30:48
User entered 'Other (OTHER)' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Oct 2020 21:30:43
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Other: Ophthalmic). Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:08:32
User entered 'Intraocular (INTRAOCULAR)'	(b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered 'Ophthalmic' reason for change: New Information	(b) (4), (b) (6)	29 Oct 2020 21:30:43
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

[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: ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS, PRODUCT: AZELASTINE HYDROCHLORIDE, PRODUCTSYNONYM: ASTELIN [AZELASTINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 15:56:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 15:56:00
Data point term sent to Coder	System	29 Oct 2020 21:31:45
Data point term sent to Coder	System	28 Oct 2020 04:56:55
Coding entries removed.	(b) (4), (b) (6)	28 Oct 2020 04:56:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS, PRODUCT: AZELASTINE HYDROCHLORIDE, PRODUCTSYNONYM: ASTELIN [AZELASTINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 11:06:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 11:06:50
Data point term sent to Coder	System	24 Sep 2020 13:05:20
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	24 Sep 2020 13:04:33
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 13:04:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	24 Sep 2020 13:04:17
User entered 'ASTELIN 0.15%' reason for change:	(b) (4), (b) (6)	24 Sep 2020 13:04:12
Data Entry Error		
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	24 Sep 2020 11:48:43
Data point term sent to Coder	System	11 Sep 2020 16:21:16
User entered 'OTC Astelin 0.15%'	(b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update indication to clarify whether 'Rhinitis Infective' or 'Allergic Rhinitis'. Please review and update as appropriate and ensure indication is reconciled with any corresponding AE or MH, if applicable. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:02:38
Query 'Per DM CLR: Please update indication to clarify whether 'Rhinitis Infective' or 'Allergic Rhinitis'. Please review and update as appropriate and ensure indication is reconciled with any corresponding AE or MH, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:31:30
User entered 'Non- Allergic RHINITIS' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Oct 2020 21:31:25
User opened query 'Per DM CLR: Please update indication to clarify whether 'Rhinitis Infective' or 'Allergic Rhinitis'. Please review and update as appropriate and ensure indication is reconciled with any corresponding AE or MH, if applicable. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:08:50
User entered 'Rhinitis'	(b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'puff (PUFF)'	(b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:23:51
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:56:39
User entered 'Nasal (NASAL)' reason for change: Per Query Resolution	(b) (4), (b) (6)	28 Oct 2020 04:56:31
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:28:00
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	(b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:33:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:33:46
Data point term sent to Coder	System	29 Oct 2020 21:32:51
Coding entries removed.	(b) (4), (b) (6)	29 Oct 2020 21:32:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 19:15:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 19:15:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 16:23:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 16:23:37
Data point term sent to Coder	System	11 Sep 2020 16:22:18

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Nexium'	(b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:06:31
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'acid reflux is GERD by the way. updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:32:54
User entered 'Acid Reflux' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Oct 2020 21:32:03
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:09:18
User entered 'GERD'	(b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	(b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

[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)	04 Nov 2020 16:10:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 16:10:25
Data point term sent to Coder	System	29 Oct 2020 21:33:53
Coding entries removed.	(b) (4), (b) (6)	29 Oct 2020 21:33:09
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)	15 Sep 2020 09:47:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 09:47:37
Data point term sent to Coder	System	11 Sep 2020 16:23:23
User entered 'Flonase 50mcg'	(b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update indication to clarify whether 'Rhinitis Infective' or 'Allergic Rhinitis'. Please review and update as appropriate and ensure indication is reconciled with any corresponding AE or MH, if applicable. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:06:43
Query 'Per DM CLR: Please update indication to clarify whether 'Rhinitis Infective' or 'Allergic Rhinitis'. Please review and update as appropriate and ensure indication is reconciled with any corresponding AE or MH, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:33:13
User entered 'Non- Allergic RHINITIS' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Oct 2020 21:33:09
User opened query 'Per DM CLR: Please update indication to clarify whether 'Rhinitis Infective' or 'Allergic Rhinitis'. Please review and update as appropriate and ensure indication is reconciled with any corresponding AE or MH, if applicable. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:09:28
User entered 'Rhinitis'	(b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2'	(b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'puff (PUFF)'	(b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:47:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:47:46
Data point term sent to Coder	System	29 Oct 2020 21:33:53
Coding entries removed.	(b) (4), (b) (6)	29 Oct 2020 21:33:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 10:13:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 10:13:49
Data point term sent to Coder	System	11 Sep 2020 16:24:24
User entered 'Diclofenac'	(b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:06:49
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:33:44
User entered 'LEFT KNEE OA' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Oct 2020 21:33:39
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:09:46
User entered 'Left Knee Pain'	(b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 14:29:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 14:29:27
Data point term sent to Coder	System	16 Oct 2020 14:28:12
User entered 'Melatonin'	(b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User entered 'Insomnia'	(b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '3'	(b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	(b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered '2x a week'	(b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

[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)	16 Oct 2020 14:30:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 14:30:31
Data point term sent to Coder	System	16 Oct 2020 14:29:14
User entered 'Multivitamin'	(b) (4), (b) (6) (b) (4)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User entered 'Good Health'	(b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:27:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:27:31
Data point term sent to Coder	System	16 Oct 2020 14:31:18
User entered 'Biotin'	(b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User entered 'Thinning of Hair'	(b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered 'UN Aug 2020'	(b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

[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) (b) (4)	16 Oct 2020 15:36:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:36:33
Data point term sent to Coder	System	16 Oct 2020 14:32:19
User entered 'Vitamin D'	(b) (4), (b) (6) (b) (4)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User entered 'Maintain Good Level'	(b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2000'	(b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'Units'	(b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:40:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:40:35
Data point term sent to Coder	System	16 Oct 2020 14:33:19
User entered 'Probiotic'	(b) (4), (b) (6) (b) (4)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User entered 'Good GI Health'	(b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'capsule (CAPSULE)'	(b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Oct 2020 06:28:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Oct 2020 06:28:12
Data point term sent to Coder	System	28 Oct 2020 04:57:56
User entered 'Tylenol'	(b) (4), (b) (6) (b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User entered 'Headache'	(b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	(b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '18 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN MIGRAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Oct 2020 06:28:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Oct 2020 06:28:14
Data point term sent to Coder	System	28 Oct 2020 04:58:56
User entered 'Excedrin Migraine'	(b) (4), (b) (6) (b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User entered 'Headache'	(b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

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

Audit	User	Time (GMT)
User entered '23 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:08:32

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	15 Oct 2020 13:23:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 13:19:30
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	15 Oct 2020 13:19:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 14:47:11
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 14:46:54
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:11:53

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:08:32

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 13:23:59

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:08:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review and record the actual medical procedure done, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:50:20
Query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review and record the actual medical procedure done, otherwise clarify.' answered with 'for the AE reported, it was asked that I put the visit here.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:48:49
User opened query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review and record the actual medical procedure done, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 05:36:16
User entered 'Dentist Visit'	(b) (4), (b) (6)	15 Oct 2020 13:23:59

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 15:23:12
User entered 'Medical History (MH)'	(b) (4), (b) (6)	15 Oct 2020 13:23:59

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:08:32

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 13:23:59

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:08:32

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(b) (4), (b) (6)	18 Nov 2020 15:39:35

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:08:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'EKG'	(b) (4), (b) (6)	18 Nov 2020 15:39:35

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	18 Nov 2020 15:39:35

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:08:32

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 15:39:35

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:08:32

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(b) (4), (b) (6)	18 Nov 2020 15:39:57

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:08:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Stress Test'	(b) (4), (b) (6)	18 Nov 2020 15:39:57

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	18 Nov 2020 15:39:57

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:08:32

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 15:39:57

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 11:08:32

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 03:48:31
User entered '28 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	18 Nov 2020 16:15:46
Query 'Data is required. Please complete.' answered with 'will record date once confirmed with provider and subject. ' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 15:57:28
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 15:57:12
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 15:57:12

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 11:08:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'CT Scan' reason for change: New Information	(b) (4), (b) (6)	18 Nov 2020 16:15:46
User entered 'CT'	(b) (4), (b) (6)	18 Nov 2020 15:57:12

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 11:08:32

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	18 Nov 2020 15:57:12

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 11:08:32

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 15:57:12

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'USA-US079-2020-MRNA-1273-P301000001'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:11
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
Un-reviewed for Safety.	System	12 Oct 2020 12:29:17
User entered 'Yes (Y)'	System	12 Oct 2020 12:29:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Bindu'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Balani'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'NJ'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered 'US'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	19 Nov 2020 19:47:07
User entered '7'	System	10 Nov 2020 20:36:29
User entered '6'	System	30 Oct 2020 12:37:25
User entered '5'	System	29 Oct 2020 13:51:21
User entered '4'	System	28 Oct 2020 19:33:58
User entered '3'	System	12 Oct 2020 12:31:21
User entered '2'	System	08 Oct 2020 12:50:39
User entered '1'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'USA-US079-2020-MRNA-1273-P301000001'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:11
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
Un-reviewed for Safety.	System	12 Oct 2020 12:29:17
User entered 'Yes (Y)'	System	12 Oct 2020 12:29:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Bindu'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Balani'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'NJ'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered 'US'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	19 Nov 2020 19:47:07
User entered '7'	System	10 Nov 2020 20:36:29
User entered '6'	System	30 Oct 2020 12:37:25
User entered '5'	System	29 Oct 2020 13:51:21
User entered '4'	System	28 Oct 2020 19:33:58
User entered '3'	System	12 Oct 2020 12:31:21
User entered '2'	System	08 Oct 2020 12:50:39
User entered '1'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:08:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '23/Sep/2020 07:39'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:08:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered '1'	(b) (4), (b) (6)	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'USA-US079-2020-MRNA-1273-P301000001'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:11
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
Un-reviewed for Safety.	System	12 Oct 2020 12:29:17
User entered 'Yes (Y)'	System	12 Oct 2020 12:29:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Bindu'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Balani'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'NJ'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered 'US'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	19 Nov 2020 19:47:07
User entered '7'	System	10 Nov 2020 20:36:29
User entered '6'	System	30 Oct 2020 12:37:25
User entered '5'	System	29 Oct 2020 13:51:21
User entered '4'	System	28 Oct 2020 19:33:58
User entered '3'	System	12 Oct 2020 12:31:21
User entered '2'	System	08 Oct 2020 12:50:39
User entered '1'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:08:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '08/Oct/2020 12:50'	System	08 Oct 2020 12:50:39

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:08:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
User entered '1'	(b) (4), (b) (6)	08 Oct 2020 12:50:39

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'USA-US079-2020-MRNA-1273-P301000001'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:11
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
Un-reviewed for Safety.	System	12 Oct 2020 12:29:17
User entered 'Yes (Y)'	System	12 Oct 2020 12:29:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Bindu'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Balani'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'NJ'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered 'US'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	19 Nov 2020 19:47:07
User entered '7'	System	10 Nov 2020 20:36:29
User entered '6'	System	30 Oct 2020 12:37:25
User entered '5'	System	29 Oct 2020 13:51:21
User entered '4'	System	28 Oct 2020 19:33:58
User entered '3'	System	12 Oct 2020 12:31:21
User entered '2'	System	08 Oct 2020 12:50:39
User entered '1'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:08:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '12/Oct/2020 12:31'	System	12 Oct 2020 12:31:21

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:08:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:50:20
User entered '1'	(b) (4), (b) (6)	12 Oct 2020 12:31:21

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'USA-US079-2020-MRNA-1273-P301000001'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:11
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
Un-reviewed for Safety.	System	12 Oct 2020 12:29:17
User entered 'Yes (Y)'	System	12 Oct 2020 12:29:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Bindu'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Balani'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'NJ'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered 'US'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	19 Nov 2020 19:47:07
User entered '7'	System	10 Nov 2020 20:36:29
User entered '6'	System	30 Oct 2020 12:37:25
User entered '5'	System	29 Oct 2020 13:51:21
User entered '4'	System	28 Oct 2020 19:33:58
User entered '3'	System	12 Oct 2020 12:31:21
User entered '2'	System	08 Oct 2020 12:50:39
User entered '1'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:08:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '28/Oct/2020 15:33'	System	28 Oct 2020 19:33:58

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:08:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:50:20
User entered '1'	(b) (4), (b) (6)	28 Oct 2020 19:33:58

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'USA-US079-2020-MRNA-1273-P301000001'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:11
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
Un-reviewed for Safety.	System	12 Oct 2020 12:29:17
User entered 'Yes (Y)'	System	12 Oct 2020 12:29:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Bindu'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Balani'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'NJ'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered 'US'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	19 Nov 2020 19:47:07
User entered '7'	System	10 Nov 2020 20:36:29
User entered '6'	System	30 Oct 2020 12:37:25
User entered '5'	System	29 Oct 2020 13:51:21
User entered '4'	System	28 Oct 2020 19:33:58
User entered '3'	System	12 Oct 2020 12:31:21
User entered '2'	System	08 Oct 2020 12:50:39
User entered '1'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:08:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '29/Oct/2020 09:51'	System	29 Oct 2020 13:51:21

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:08:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 12:37:14
User entered '1'	(b) (4), (b) (6)	29 Oct 2020 13:51:21

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'USA-US079-2020-MRNA-1273-P301000001'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:11
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
Un-reviewed for Safety.	System	12 Oct 2020 12:29:17
User entered 'Yes (Y)'	System	12 Oct 2020 12:29:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Bindu'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Balani'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'NJ'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered 'US'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	19 Nov 2020 19:47:07
User entered '7'	System	10 Nov 2020 20:36:29
User entered '6'	System	30 Oct 2020 12:37:25
User entered '5'	System	29 Oct 2020 13:51:21
User entered '4'	System	28 Oct 2020 19:33:58
User entered '3'	System	12 Oct 2020 12:31:21
User entered '2'	System	08 Oct 2020 12:50:39
User entered '1'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 11:08:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '30/Oct/2020 08:37'	System	30 Oct 2020 12:37:25

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 11:08:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:36:09
User entered '1'	(b) (4), (b) (6)	30 Oct 2020 12:37:25

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'USA-US079-2020-MRNA-1273-P301000001'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:11
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
Un-reviewed for Safety.	System	12 Oct 2020 12:29:17
User entered 'Yes (Y)'	System	12 Oct 2020 12:29:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Bindu'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Balani'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'NJ'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered 'US'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	19 Nov 2020 19:47:07
User entered '7'	System	10 Nov 2020 20:36:29
User entered '6'	System	30 Oct 2020 12:37:25
User entered '5'	System	29 Oct 2020 13:51:21
User entered '4'	System	28 Oct 2020 19:33:58
User entered '3'	System	12 Oct 2020 12:31:21
User entered '2'	System	08 Oct 2020 12:50:39
User entered '1'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 11:08:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '10/Nov/2020 15:36'	System	10 Nov 2020 20:36:29

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 11:08:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:46:51
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 20:36:29

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'USA-US079-2020-MRNA-1273-P301000001'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:11
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
Un-reviewed for Safety.	System	12 Oct 2020 12:29:17
User entered 'Yes (Y)'	System	12 Oct 2020 12:29:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Bindu'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Balani'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'NJ'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered 'US'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	19 Nov 2020 19:47:07
User entered '7'	System	10 Nov 2020 20:36:29
User entered '6'	System	30 Oct 2020 12:37:25
User entered '5'	System	29 Oct 2020 13:51:21
User entered '4'	System	28 Oct 2020 19:33:58
User entered '3'	System	12 Oct 2020 12:31:21
User entered '2'	System	08 Oct 2020 12:50:39
User entered '1'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 11:08:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '19/Nov/2020 19:47'	System	19 Nov 2020 19:47:07

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 11:08:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	19 Nov 2020 19:47:07