

US3442031 (Prod: Benchmark Research - Fort Worth)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:25:48

All time stamps listed in this document are displayed in GMT

US3442031

Form: Participant Creation

Generated On: 26 Nov 2020 09:25:48

[Participant ID](#)

US3442031

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

US3442031

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3442031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:48

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:48

Date of Informed Consent (<i>dd MMM yyyy</i>)	18 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:25:48

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:25:48

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:48

Condition	THROMBOPHILLIA
Start date (dd MMM yyyy)	21 NOV 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:48

Condition	THROMBUS
Start date (dd MMM yyyy)	UN NOV 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN NOV 2008
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2007
Start Year (derived)	2007
Stop Month and Year (derived)	NOV 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:48

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

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:48

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

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:48

Condition	CHOLELITHIASIS
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:48

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

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:48

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

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:48

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

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:48

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:48

Condition	POST-MENOPAUSAL
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 (11)

Generated On: 26 Nov 2020 09:25:48

Condition	MORPHINE ALLERGY (ITCHING AND CRAWLING FEELING)
Start date (dd MMM yyyy)	UN UNK 1992
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 1992
Start Year (derived)	1992
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:48

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:48

Condition	RECURRENT KIDNEY STONES
Start date (dd MMM yyyy)	UN UNK 1982
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 1982
Start Year (derived)	1982
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:48

Condition	GASTRIC SLEEVE
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)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:48

Condition	ABDOMINOPLASTY
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)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:48

Condition	RECURRENT KIDNEY STONES
Start date (dd MMM yyyy)	UN UNK 1982
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 1982
Start Year (derived)	1982
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:25:48

Condition	BREAST AUGMENTATION
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)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	18 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:50 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 16:50
Height (<i>xxx.x</i>)	66.5 in
Weight (<i>xxx.x</i>)	180.6 lb
BMI (<i>xxx.x</i>)	28.77295 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 09:25:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:48

Date of assessment (<i>dd MMM yyyy</i>)	18 AUG 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 (<i>dd MMM yyyy</i>) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 2010
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

Occupational Risk

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

Specify

Location and Living Circumstances Risk (check all that apply)

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:48

What was the date of randomization? (dd MMM yyyy) 18 AUG 2020

What was the participant's randomization number? 143948

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 09:25:48

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 09:25:48

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)	18 AUG 2020
Time of assessment (00:00-23:59)	16:50 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 16:50
Temperature (xxx.x)	97.4 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 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 09:25:48

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)	18 AUG 2020
Time of assessment (00:00-23:59)	19:00 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 19:00
Temperature (xxx.x)	96.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:48

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

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)	18 AUG 2020
What was the treatment time? (00:00-23:59)	18:21 (24 HR)
Treatment Date and Time (derived)	18 AUG 2020 18:21
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 09:25:48

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	18 AUG 2020
Collection time (<i>00:00-23:59</i>)	17:16 (24 HR)
Collection date and time (derived)	18 AUG 2020 17:16

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:25:48

Collection date (<i>dd MMM yyyy</i>)			18 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:12	18 AUG 2020 17:12
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

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 09:25:48

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

97.4 °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

18 AUG 2020 19:05

PC Open Date & Time

18 AUG 2020 18:41

PC Close Date & Time

18 AUG 2020 21:11

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 18 AUG 2020 22:06

PC Close Date & Time 19 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

19 AUG 2020 22:34

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 22:41

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

22 AUG 2020 07:20

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 23:59

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

23 AUG 2020 21:50

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

24 AUG 2020 22:41

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

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

18 AUG 2020 19:05

PC Open Date & Time

18 AUG 2020 18:41

PC Close Date & Time

18 AUG 2020 21:11

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

18 AUG 2020 22:06

PC Close Date & Time

19 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 22:35

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:48

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

20 AUG 2020 22:42

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:48

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

22 AUG 2020 07:20

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:48

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

23 AUG 2020 00:00

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:48

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

23 AUG 2020 21:50

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:48

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

24 AUG 2020 22:41

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 19:06
PC Open Date & Time	18 AUG 2020 18:41
PC Close Date & Time	18 AUG 2020 21:11

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

18 AUG 2020 22:06

PC Close Date & Time

19 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

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 ☒

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

Yes ☐	
PC Time stamp	19 AUG 2020 22:36
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

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 ☒

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

Yes ☐	
PC Time stamp	20 AUG 2020 22:43
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

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 ☒

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

Yes ☐	
PC Time stamp	22 AUG 2020 07:20
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:48

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 ☒

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:48

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

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

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 ☒

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

Yes ☐	
PC Time stamp	24 AUG 2020 09:56
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

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 ☒

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

Yes ☐	
PC Time stamp	24 AUG 2020 22:42
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3442031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

Was Contact Attempted?

Yes ☒

No ☐

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

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442031

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442031

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442031

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	10:17 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 10:17
Temperature (xxx.x)	97.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 11:50
Temperature (xxx.x)	97.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3442031

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

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)	21 SEP 2020
What was the treatment time? (00:00-23:59)	11:20 (24 HR)
Treatment Date and Time (derived)	21 SEP 2020 11:20
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

US3442031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:48

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	21 SEP 2020
Collection time (<i>00:00-23:59</i>)	10:25 (24 HR)
Collection date and time (derived)	21 SEP 2020 10:25

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:25:48

Collection date (<i>dd MMM yyyy</i>)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:30	21 SEP 2020 10:30
Nasopharyngeal Swab 2	No		

US3442031

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

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

97.3 °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

21 SEP 2020 11:59

PC Open Date & Time

21 SEP 2020 11:40

PC Close Date & Time

21 SEP 2020 14:10

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

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 97.5 °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	21 SEP 2020 21:47
PC Open Date & Time	21 SEP 2020 15:05
PC Close Date & Time	22 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:48

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	99.5 °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):

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

PC Time Stamp	22 SEP 2020 22:40
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:48

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 99.5 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 23 SEP 2020 22:33

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

24 SEP 2020 22:26

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE in °F**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

26 SEP 2020 12:10

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

28 SEP 2020 07:52

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

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

21 SEP 2020 11:59

PC Open Date & Time

21 SEP 2020 11:40

PC Close Date & Time

21 SEP 2020 14:10

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 21:48

PC Open Date & Time

21 SEP 2020 15:05

PC Close Date & Time

22 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 22:41

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 22:34

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:48

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

24 SEP 2020 22:27

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:48

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

26 SEP 2020 12:11

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:48

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

28 SEP 2020 07:52

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 12:00
PC Open Date & Time	21 SEP 2020 11:40
PC Close Date & Time	21 SEP 2020 14:10

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 21:49
PC Open Date & Time	21 SEP 2020 15:05
PC Close Date & Time	22 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

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 ☒

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

Yes ☐	
PC Time stamp	22 SEP 2020 22:42
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

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 ☒

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

Yes ☐	
PC Time stamp	23 SEP 2020 22:35
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

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 ☒

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

Yes ☐	
PC Time stamp	24 SEP 2020 22:27
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:48

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

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

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 ☒

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

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

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

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 ☒

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

Yes ☐	
PC Time stamp	28 SEP 2020 07:53
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3442031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442031

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442031

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442031

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

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

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

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)	

US3442031

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:48

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.

US3442031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:48

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	16 OCT 2020
Collection time (<i>00:00-23:59</i>)	09:52 (24 HR)
Collection date and time (derived)	16 OCT 2020 09:52

US3442031

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 OCT 2020 16:38:51
Patient Cloud Open Date & Time	18 OCT 2020 00:01
Patient Cloud Close Date & Time	22 OCT 2020 23:59

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

27 OCT 2020 12:01:01

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 NOV 2020 10:57:30
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 12:00:52

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 MAR 2021 00:01

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08 MAR 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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°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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 JAN 2022 00:01

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10 JAN 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 FEB 2022 00:01

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21 FEB 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 FEB 2022 00:01

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28 FEB 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 MAR 2022 00:01

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07 MAR 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 APR 2022 00:01

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02 MAY 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 MAY 2022 00:01

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09 MAY 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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°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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 MAY 2022 00:01

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16 MAY 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 MAY 2022 00:01

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30 MAY 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

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02 JUN 2022 00:01

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06 JUN 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

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09 JUN 2022 00:01

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13 JUN 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

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20 JUN 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 JUN 2022 00:01

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27 JUN 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

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04 JUL 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 JUL 2022 00:01

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11 JUL 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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

Date and time of submission

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18 JUL 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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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25 JUL 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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°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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3442031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

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

US3442031

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3442031

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:25:48

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 ☐

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Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:25:48

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:25:48

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

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)	0

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

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

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

AEID	USA-US017-2020-MRNA-1273-P30 1000003
Adverse event	DEEP VEIN THROMBOSIS (LEFT LEG)
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)	3 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)	4 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	True
Hospital Admission Date (dd MMM yyyy)	3 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	4 NOV 2020
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 09:25:48

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT HOSPITALIZED OVERNIGHT FOR DEEP VEIN THROMBOSIS. SUBJECT WAS RELEASED AND MEDICAL RECORDS HAVE BEEN REQUESTED.
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
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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

AEID	USA-US017-2020-MRNA-1273-P30 1000003
Adverse event	PULMONARY EMBOLISM
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)	3 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)	4 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	True
Hospital Admission Date (dd MMM yyyy)	3 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	4 NOV 2020
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 09:25:48

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT HOSPITALIZED OVERNIGHT FOR PULMONARY EMBOLISM. SUBJECT WAS RELEASED AND MEDICAL RECORDS HAVE BEEN REQUESTED
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
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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

AEID	
Adverse event	LEFT CALF 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)	1 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)	12 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 (5)

Generated On: 26 Nov 2020 09:25:48

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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

AEID	
Adverse event	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)	4 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)	
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 (6)

Generated On: 26 Nov 2020 09:25:48

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

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

AEID	
Adverse event	SHORTNESS OF BREATH
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	4 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)	12 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 (7)

Generated On: 26 Nov 2020 09:25:48

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

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

AEID	
Adverse event	NAUSEA
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)	26 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	27 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	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 09:25:48

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)	0

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

AEID	
Adverse event	VOMITING
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)	26 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	27 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	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 09:25:48

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 09:25:48

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

Name of Medication	PROTONIX (PANTOPRAZOLE)
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

Name of Medication	AMITRIPTYLINE
Prophylaxis	Yes ☐ No ☒
Indication	ANXIETY
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 ☐

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

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

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

Name of Medication	SERTRALINE
Prophylaxis	Yes ☐ No ☒
Indication	ANXIETY
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 ☐

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

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

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

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

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ☒
Indication	INJECTION SITE PAIN
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 ☐

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

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

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

Name of Medication	ZOFRAN
Prophylaxis	Yes ☐ No ☒
Indication	NAUSEA
Dose per administration	8
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 ☐

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

	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)	26 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		27 AUG 2020
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ☒
Indication	ELEVATED TEMPERATURE, BODY ACHES, FATIGUE
Dose per administration	1000
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☒ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy) 24 SEP 2020		
Was this medication taken for solicited event?	Yes ☒	No ☐
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

Name of Medication	APIXABAN
Prophylaxis	Yes ☐ No ☒
Indication	BLOOD CLOTS
Dose per administration	5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
2 TABS BID FOR 7 DAYS THEN 1 TAB BID	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		4 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

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

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

	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)		4 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		12 NOV 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	☐

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:25:48

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3442031

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:25:48

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

US3442031

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:25:48

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 ☐

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

SAEID	USA-US017-2020-MRNA-1273-P301000003
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4505 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:25:48

SAEID	USA-US017-2020-MRNA-1273-P301000003
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4505 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	09/NOV/2020 18:02
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

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:25:48

SAEID	USA-US017-2020-MRNA-1273-P301000003
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4505 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	16/NOV/2020 12:57
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

US3442031 (Prod: Benchmark Research - Fort Worth)

US3442031

Form: Participant Creation

Generated On: 26 Nov 2020 09:25:48

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3442031'	RWS_ENDPOINT ENDPOINT (b) (4) 	18 Aug 2020 21:39:18

US3442031

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:02

US3442031

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '18 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	18 Aug 2020 21:39:19

US3442031

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:02

US3442031

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	18 Aug 2020 22:57:02

US3442031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:48

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1965'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	18 Aug 2020 21:39:20

US3442031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:48

[Age](#)

Audit	User	Time (GMT)
User entered '55'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:48

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:48

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '55'	System	18 Aug 2020 22:57:44

US3442031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:48

Sex

Audit	User	Time (GMT)
User entered 'Female (F)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:48

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:48

White

Audit	User	Time (GMT)
User entered '1'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:48

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:48

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:48

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:48

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:48

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:48

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:48

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:48

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:44

US3442031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	18 Aug 2020 22:57:44

US3442031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2020'	System	18 Aug 2020 22:57:44

US3442031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:48

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:44

US3442031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:44

US3442031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:44

US3442031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:48

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:44

US3442031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:48

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:44

US3442031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:48

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	18 Aug 2020 21:39:19

US3442031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:48

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 22:57:49

US3442031

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:49

US3442031

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:25:48

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:14:55

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Coagulopathies and bleeding diatheses (excl thrombocytopenic), HLT: Coagulopathies, PT: Hypercoagulation, LLT: Thrombophilia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 07:48:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 07:48:24
Data point term sent to Coder	System	18 Aug 2020 23:18:48
User entered 'THROMBOPHILLIA'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '21 Nov 2008'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Nov 2008'	System	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2008'	System	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Non-site specific embolism and thrombosis, PT: Thrombosis, LLT: Thrombus - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:36:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:36:40
Data point term sent to Coder	System	18 Aug 2020 23:19:49
User entered 'THROMBUS'	Melody Dufrene (b) (4)	18 Aug 2020 23:19:30
	(b) (4)	

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'UN Nov 2007'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'UN Nov 2008'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Nov 2007'	System	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2007'	System	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Nov 2008'	System	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2008'	System	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:36:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:36:40
Data point term sent to Coder	System	18 Aug 2020 23:21:52
User entered 'HEARTBURN'	Melody Dufrene (b) (4)	18 Aug 2020 23:21:30
	(b) (4)	

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2016'	System	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 00:45:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 00:45:18
Data point term sent to Coder	System	19 Aug 2020 00:44:24
User entered 'Hypothyroidism'	Alma Guel (b) (4)	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Alma Guel (b) (4)	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alma Guel (b) (4)	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2017'	System	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 15:01:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 15:01:36
Data point term sent to Coder	System	25 Aug 2020 15:00:42
User entered 'CHOLELITHIASIS'	Melody Dufrene (b) (4)	25 Aug 2020 14:59:44
	(b) (4)	

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'UN UNK 2013'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'UN UNK 2013'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2013'	System	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2013'	System	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:48

[Condition](#)

Audit	User	Time (GMT)
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)	25 Aug 2020 15:08:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 15:08:34
Data point term sent to Coder	System	25 Aug 2020 15:08:05
User entered 'ANXIETY'	Melody Dufrene (b) (4)	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016' reason for change: Data Entry Error	John Villegas (b) (4) (b) (4)	01 Oct 2020 17:29:32
User entered 'UN UNK 2017'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	01 Oct 2020 17:29:32
User entered 'Jan 2017'	System	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2016'	System	01 Oct 2020 17:29:32
User entered '2017'	System	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 15:16:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 15:16:35
Data point term sent to Coder	System	25 Aug 2020 15:15:21
User entered 'APPENDECTOMY'	Melody Dufrene (b) (4)	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2010'	System	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2010'	System	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 15:16:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 15:16:35
Data point term sent to Coder	System	25 Aug 2020 15:15:21
User entered 'APPENDICITIS'	Melody Dufrene (b) (4)	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2010'	System	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2010'	System	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 15:17:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 15:17:30
Data point term sent to Coder	System	25 Aug 2020 15:16:23
User entered 'CHOLECYSTECTOMY'	Melody Dufrene (b) (4)	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'UN UNK 2013'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'UN UNK 2013'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2013'	System	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2013'	System	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 20:57:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	08 Oct 2020 20:57:59
Data point term sent to Coder	System	08 Oct 2020 14:21:38
User entered 'post-menopausal'	(b) (4), (b) (6)	08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	(b) (4), (b) (6)	08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2010'	System	08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 19:03:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 19:03:51
Data point term sent to Coder	System	14 Nov 2020 16:36:20
User entered 'Morphine Allergy (Itching and crawling feeling)'	Alma Guel (b) (4)	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'un UNK 1992'	Alma Guel (b) (4)	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alma Guel (b) (4)	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 1992'	System	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '1992'	System	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 16:37:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 16:37:50
Data point term sent to Coder	System	14 Nov 2020 16:37:21
User entered 'Obesity'	Alma Guel (b) (4)	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'un UNK 1990'	Alma Guel (b) (4)	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	Alma Guel (b) (4)	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '1990'	System	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2012'	System	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis recurrent - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 16:38:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 16:38:50
Data point term sent to Coder	System	14 Nov 2020 16:38:22
User entered 'Recurrent Kidney Stones'	Alma Guel (b) (4)	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'un UNK 1982'	Alma Guel (b) (4)	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alma Guel (b) (4)	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 1982'	System	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '1982'	System	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastrectomy, LLT: Sleeve gastrectomy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 16:39:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 16:39:50
Data point term sent to Coder	System	14 Nov 2020 16:39:22
User entered 'Gastric Sleeve'	Alma Guel (b) (4)	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	Alma Guel (b) (4)	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	Alma Guel (b) (4)	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2012'	System	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2012'	System	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Abdominal therapeutic procedures NEC, PT: Abdominoplasty, LLT: Abdominoplasty - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 16:40:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 16:40:57
Data point term sent to Coder	System	14 Nov 2020 16:40:23
User entered 'abdominoplasty'	Alma Guel (b) (4)	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Alma Guel (b) (4)	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Alma Guel (b) (4)	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2015'	System	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2015'	System	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis recurrent - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:01:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:01:08
Data point term sent to Coder	System	23 Nov 2020 19:27:21
User entered 'recurrent kidney stones'	Alma Guel (b) (4)	23 Nov 2020 19:26:59

US3442031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'un UNK 1982'	Alma Guel (b) (4)	23 Nov 2020 19:26:59

US3442031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	23 Nov 2020 19:26:59

US3442031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alma Guel (b) (4)	23 Nov 2020 19:26:59

US3442031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	23 Nov 2020 19:26:59

US3442031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	23 Nov 2020 19:26:59

US3442031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 1982'	System	23 Nov 2020 19:26:59

US3442031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '1982'	System	23 Nov 2020 19:26:59

US3442031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:26:59

US3442031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:26:59

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:25:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Mammoplasty, LLT: Augmentation mammoplasty - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:03:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:03:04
Data point term sent to Coder	System	23 Nov 2020 19:29:24
User entered 'Breast Augmentation'	Alma Guel (b) (4)	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Alma Guel (b) (4)	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:25:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Alma Guel (b) (4)	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:25:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2015'	System	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '2015'	System	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '16:50'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '18 Aug 2020 16:50'	System	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '66.5' in	Melody Dufrene (b) (4)	25 Aug 2020 15:17:52
DataPoint set to visible.	(b) (4) System	18 Aug 2020 22:57:49

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '180.6' lb	Melody Dufrene (b) (4)	25 Aug 2020 15:17:52
DataPoint set to visible.	(b) (4) System	18 Aug 2020 22:57:49

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '28.77295'	System	17 Sep 2020 00:13:09
User entered '28.8'	System	25 Aug 2020 15:17:52
DataPoint set to visible.	System	18 Aug 2020 22:57:49

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	25 Aug 2020 15:17:52
DataPoint set to visible.	System	18 Aug 2020 22:57:49

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:18:15

US3442031

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:18:15

US3442031

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:20:13

US3442031

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:48

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:20:13

US3442031

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:48

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 12:16:43
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:22:50
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:27:41
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:20:13

US3442031

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:48

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:20:13

US3442031

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:20:13

US3442031

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:48

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:20:13

US3442031

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:20:13

US3442031

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:48

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:20:13

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

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)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

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)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

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)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

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)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

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)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

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'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '1'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:48

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:58:01

US3442031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:58:01

US3442031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:58:05
User entered 'Home (Home)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:58:01

US3442031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	18 Aug 2020 22:58:01

US3442031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '18 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	18 Aug 2020 22:39:27

US3442031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:48

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:27:11
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:27:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Aug 2020 22:39:27
User entered '143948' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	18 Aug 2020 22:39:27

US3442031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 05:48:39
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'correction submitted to endpoint' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 23:14:57
Amendment Manager: User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	30 Sep 2020 21:00:06
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	30 Sep 2020 21:00:06
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	18 Aug 2020 22:59:06
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 22:39:27

US3442031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:48

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)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:59:06

US3442031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:59:06

US3442031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:59:06

US3442031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:48

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:59:06

US3442031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:48

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:59:06

US3442031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 15:53:16
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:35:21
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:25:31

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:48

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:48

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:48

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:48

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '16:50'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '18 Aug 2020 16:50'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.4' F	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

Pulse (xxx)

Audit	User	Time (GMT)
User entered '71'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '14'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '116'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '81'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:48

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:48

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '19:00'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '18 Aug 2020 19:00'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM, Response noted; However please advice if the out of range value is CS/NCS. If CS, please report as AE as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 09:57:32
Query 'Per CDM, Response noted; However please advice if the out of range value is CS/NCS. If CS, please report as AE as appropriate.' answered with 'Temp is correct as entered. It was rechecked and remained the same. It is not clinically significant.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 19:58:05
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 12:46:31
User opened query 'Per CDM, Response noted; However please advice if the out of range value is CS/NCS. If CS, please report as AE as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 12:46:27
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.' answered with 'temp is correct as entered. It was rechecked and remained the same.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 15:16:39
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 00:13:09
User entered '96.7' F	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '13'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '121'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:48

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:23:03

US3442031

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:23:03

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '18:21'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '18 Aug 2020 18:21'	System	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:23:56

US3442031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:23:56

US3442031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '17:16'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:23:56

US3442031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '18 Aug 2020 17:16'	System	25 Aug 2020 15:23:56

US3442031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:25:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:24:13

US3442031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:48

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Melody Dufrene (b) (4)	25 Aug 2020 15:24:13

US3442031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:24:13

US3442031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '17:12'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:24:13

US3442031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '18 Aug 2020 17:12'	System	25 Aug 2020 15:24:13

US3442031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:48

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Melody Dufrene (b) (4)	25 Aug 2020 15:24:13

US3442031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:24:13

US3442031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:24:13

US3442031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 15:24:13

US3442031

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:24:19

US3442031

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:24:19

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:04:53', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'bf032f60-d4e9-4a03-bfd8-65e03a71a89f'	System	19 Aug 2020 00:05:22
User entered 'Yes (Y)'	System	19 Aug 2020 00:05:22

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:03', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'bf032f60-d4e9-4a03-bfd8-65e03a71a89f'	System	19 Aug 2020 00:05:22
User entered '97.4'	System	19 Aug 2020 00:05:22

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:15', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'bf032f60-d4e9-4a03-bfd8-65e03a71a89f'	System	19 Aug 2020 00:05:22
User entered 'No (N)'	System	19 Aug 2020 00:05:22

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:20', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'bf032f60-d4e9-4a03-bfd8-65e03a71a89f'	System	19 Aug 2020 00:05:22
User entered '18 Aug 2020 19:05'	System	19 Aug 2020 00:05:22

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 18:41'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 21:11'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 22:06'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 2'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:33:43', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f7b8f7ae-361f-4a8f-99f2-f698c42d4735'	System	20 Aug 2020 03:34:06
User entered 'Yes (Y)'	System	20 Aug 2020 03:34:06

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:33:51', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f7b8f7ae-361f-4a8f-99f2-f698c42d4735'	System	20 Aug 2020 03:34:06
User entered '96.5'	System	20 Aug 2020 03:34:06

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:33:56', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f7b8f7ae-361f-4a8f-99f2-f698c42d4735'	System	20 Aug 2020 03:34:06
User entered 'No (N)'	System	20 Aug 2020 03:34:06

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:34:04', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f7b8f7ae-361f-4a8f-99f2-f698c42d4735'	System	20 Aug 2020 03:34:06
User entered '19 Aug 2020 22:34'	System	20 Aug 2020 03:34:06

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 3'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:41:06', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'dae87378-bccc-4287-b80d-3927c83d8c9d'	System	21 Aug 2020 03:41:39
User entered 'Yes (Y)'	System	21 Aug 2020 03:41:39

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:48

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:41:19', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'dae87378-bccc-4287-b80d-3927c83d8c9d'	System	21 Aug 2020 03:41:39
User entered '97.6'	System	21 Aug 2020 03:41:39

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:41:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'dae87378-bccc-4287-b80d-3927c83d8c9d'	System	21 Aug 2020 03:41:39
User entered 'No (N)'	System	21 Aug 2020 03:41:39

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:41:34', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'dae87378-bccc-4287-b80d-3927c83d8c9d'	System	21 Aug 2020 03:41:39
User entered '20 Aug 2020 22:41'	System	21 Aug 2020 03:41:39

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 4'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:19:45', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c9f27a2f-00ee-4bb0-abce-8f1b8e6e10c5'	System	22 Aug 2020 12:20:08
User entered 'Yes (Y)'	System	22 Aug 2020 12:20:08

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:19:53', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c9f27a2f-00ee-4bb0-abce-8f1b8e6e10c5'	System	22 Aug 2020 12:20:08
User entered '97.6'	System	22 Aug 2020 12:20:08

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:19:57', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c9f27a2f-00ee-4bb0-abce-8f1b8e6e10c5'	System	22 Aug 2020 12:20:08
User entered 'No (N)'	System	22 Aug 2020 12:20:08

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:03', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c9f27a2f-00ee-4bb0-abce-8f1b8e6e10c5'	System	22 Aug 2020 12:20:08
User entered '22 Aug 2020 07:20'	System	22 Aug 2020 12:20:08

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 5'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T23:59:32', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '776893fc-f67d-4375-b31d-62175c1cd433'	System	23 Aug 2020 04:59:56
User entered 'Yes (Y)'	System	23 Aug 2020 04:59:56

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T23:59:40', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '776893fc-f67d-4375-b31d-62175c1cd433'	System	23 Aug 2020 04:59:56
User entered '97.8'	System	23 Aug 2020 04:59:56

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T23:59:47', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '776893fc-f67d-4375-b31d-62175c1cd433'	System	23 Aug 2020 04:59:56
User entered 'No (N)'	System	23 Aug 2020 04:59:56

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T23:59:53', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '776893fc-f67d-4375-b31d-62175c1cd433'	System	23 Aug 2020 04:59:56
User entered '22 Aug 2020 23:59'	System	23 Aug 2020 04:59:56

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 6'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T21:50:06', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '4b972f10-173a-4b72-9376-bbfb2ee39b62'	System	24 Aug 2020 02:50:29
User entered 'Yes (Y)'	System	24 Aug 2020 02:50:29

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T21:50:18', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '4b972f10-173a-4b72-9376-bbfb2ee39b62'	System	24 Aug 2020 02:50:29
User entered '97.8'	System	24 Aug 2020 02:50:29

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T21:50:22', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '4b972f10-173a-4b72-9376-bbfb2ee39b62'	System	24 Aug 2020 02:50:29
User entered 'No (N)'	System	24 Aug 2020 02:50:29

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T21:50:26', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '4b972f10-173a-4b72-9376-bbfb2ee39b62'	System	24 Aug 2020 02:50:29
User entered '23 Aug 2020 21:50'	System	24 Aug 2020 02:50:29

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 7'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:07', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f93240aa-e4c7-4ae9-9ebd-9126ffdd32a6'	System	25 Aug 2020 03:41:28
User entered 'Yes (Y)'	System	25 Aug 2020 03:41:28

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:17', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f93240aa-e4c7-4ae9-9ebd-9126ffdd32a6'	System	25 Aug 2020 03:41:28
User entered '97.7'	System	25 Aug 2020 03:41:28

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:21', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f93240aa-e4c7-4ae9-9ebd-9126ffdd32a6'	System	25 Aug 2020 03:41:28
User entered 'No (N)'	System	25 Aug 2020 03:41:28

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:27', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f93240aa-e4c7-4ae9-9ebd-9126ffdd32a6'	System	25 Aug 2020 03:41:28
User entered '24 Aug 2020 22:41'	System	25 Aug 2020 03:41:28

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:31', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'ef41d5fd-bace-4772-804d-5e8371e96fbf'	System	19 Aug 2020 00:05:48
User entered 'None (1)'	System	19 Aug 2020 00:05:48

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:34', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'ef41d5fd-bace-4772-804d-5e8371e96fbf'	System	19 Aug 2020 00:05:48
User entered 'No (N)'	System	19 Aug 2020 00:05:48

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:38', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'ef41d5fd-bace-4772-804d-5e8371e96fbf'	System	19 Aug 2020 00:05:48
User entered 'No (N)'	System	19 Aug 2020 00:05:48

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:41', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'ef41d5fd-bace-4772-804d-5e8371e96fbf'	System	19 Aug 2020 00:05:48
User entered 'None (1)'	System	19 Aug 2020 00:05:48

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:44', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'ef41d5fd-bace-4772-804d-5e8371e96fbf'	System	19 Aug 2020 00:05:48
User entered '18 Aug 2020 19:05'	System	19 Aug 2020 00:05:48

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 18:41'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 21:11'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 22:06'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 2'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:34:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2843c14e-4fef-4dc5-9ca0-1cd3a4e1f33e'	System	20 Aug 2020 03:35:28
User entered 'Does not interfere with activity (2)'	System	20 Aug 2020 03:35:28

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:34:29', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2843c14e-4fef-4dc5-9ca0-1cd3a4e1f33e'	System	20 Aug 2020 03:35:28
User entered 'No (N)'	System	20 Aug 2020 03:35:28

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:34:48', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2843c14e-4fef-4dc5-9ca0-1cd3a4e1f33e'	System	20 Aug 2020 03:35:28
User entered 'No (N)'	System	20 Aug 2020 03:35:28

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:35:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2843c14e-4fef-4dc5-9ca0-1cd3a4e1f33e'	System	20 Aug 2020 03:35:28
User entered 'None (1)'	System	20 Aug 2020 03:35:28

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:35:27', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2843c14e-4fef-4dc5-9ca0-1cd3a4e1f33e'	System	20 Aug 2020 03:35:28
User entered '19 Aug 2020 22:35'	System	20 Aug 2020 03:35:28

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 3'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:42:11', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '6978ce2d-1349-4024-b82c-5c2bd6b61ead'	System	21 Aug 2020 03:42:35
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 03:42:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:42:17', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '6978ce2d-1349-4024-b82c-5c2bd6b61ead'	System	21 Aug 2020 03:42:35
User entered 'No (N)'	System	21 Aug 2020 03:42:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:42:22', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '6978ce2d-1349-4024-b82c-5c2bd6b61ead'	System	21 Aug 2020 03:42:35
User entered 'No (N)'	System	21 Aug 2020 03:42:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:42:28', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '6978ce2d-1349-4024-b82c-5c2bd6b61ead'	System	21 Aug 2020 03:42:35
User entered 'None (1)'	System	21 Aug 2020 03:42:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:42:32', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '6978ce2d-1349-4024-b82c-5c2bd6b61ead'	System	21 Aug 2020 03:42:35
User entered '20 Aug 2020 22:42'	System	21 Aug 2020 03:42:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 4'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:48

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:14', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0b8ea75e-7174-4696-84b1-4376a91a3db7'	System	22 Aug 2020 12:20:30
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 12:20:30

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:18', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0b8ea75e-7174-4696-84b1-4376a91a3db7'	System	22 Aug 2020 12:20:30
User entered 'No (N)'	System	22 Aug 2020 12:20:30

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:22', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0b8ea75e-7174-4696-84b1-4376a91a3db7'	System	22 Aug 2020 12:20:30
User entered 'No (N)'	System	22 Aug 2020 12:20:30

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:25', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0b8ea75e-7174-4696-84b1-4376a91a3db7'	System	22 Aug 2020 12:20:30
User entered 'None (1)'	System	22 Aug 2020 12:20:30

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:28', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0b8ea75e-7174-4696-84b1-4376a91a3db7'	System	22 Aug 2020 12:20:30
User entered '22 Aug 2020 07:20'	System	22 Aug 2020 12:20:30

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 5'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:48

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:03', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7602ada6-ef4c-4eb2-ac72-a19725587408'	System	23 Aug 2020 05:00:21
User entered 'None (1)'	System	23 Aug 2020 05:00:21

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:06', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7602ada6-ef4c-4eb2-ac72-a19725587408'	System	23 Aug 2020 05:00:21
User entered 'No (N)'	System	23 Aug 2020 05:00:21

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:09', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7602ada6-ef4c-4eb2-ac72-a19725587408'	System	23 Aug 2020 05:00:21
User entered 'No (N)'	System	23 Aug 2020 05:00:21

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:14', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7602ada6-ef4c-4eb2-ac72-a19725587408'	System	23 Aug 2020 05:00:21
User entered 'None (1)'	System	23 Aug 2020 05:00:21

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:18', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7602ada6-ef4c-4eb2-ac72-a19725587408'	System	23 Aug 2020 05:00:21
User entered '23 Aug 2020 00:00'	System	23 Aug 2020 05:00:21

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 6'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:48

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T21:50:35', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f546132e-a350-4ade-a309-9d699381f9ba'	System	24 Aug 2020 02:50:51
User entered 'None (1)'	System	24 Aug 2020 02:50:51

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T21:50:38', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f546132e-a350-4ade-a309-9d699381f9ba'	System	24 Aug 2020 02:50:51
User entered 'No (N)'	System	24 Aug 2020 02:50:51

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T21:50:41', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f546132e-a350-4ade-a309-9d699381f9ba'	System	24 Aug 2020 02:50:51
User entered 'No (N)'	System	24 Aug 2020 02:50:51

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T21:50:45', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f546132e-a350-4ade-a309-9d699381f9ba'	System	24 Aug 2020 02:50:51
User entered 'None (1)'	System	24 Aug 2020 02:50:51

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T21:50:49', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f546132e-a350-4ade-a309-9d699381f9ba'	System	24 Aug 2020 02:50:51
User entered '23 Aug 2020 21:50'	System	24 Aug 2020 02:50:51

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 7'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:48

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:33', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '1cf52855-0429-4a6e-987e-c5f4609afdc3'	System	25 Aug 2020 03:41:50
User entered 'None (1)'	System	25 Aug 2020 03:41:50

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:36', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '1cf52855-0429-4a6e-987e-c5f4609afdc3'	System	25 Aug 2020 03:41:50
User entered 'No (N)'	System	25 Aug 2020 03:41:50

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:40', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '1cf52855-0429-4a6e-987e-c5f4609afdc3'	System	25 Aug 2020 03:41:50
User entered 'No (N)'	System	25 Aug 2020 03:41:50

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:45', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '1cf52855-0429-4a6e-987e-c5f4609afdc3'	System	25 Aug 2020 03:41:50
User entered 'None (1)'	System	25 Aug 2020 03:41:50

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:49', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '1cf52855-0429-4a6e-987e-c5f4609afdc3'	System	25 Aug 2020 03:41:50
User entered '24 Aug 2020 22:41'	System	25 Aug 2020 03:41:50

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:50', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2ed3b29e-4ff0-4a93-8a61-4094a8866077'	System	19 Aug 2020 00:06:19
User entered 'None (0)'	System	19 Aug 2020 00:06:19

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:53', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2ed3b29e-4ff0-4a93-8a61-4094a8866077'	System	19 Aug 2020 00:06:19
User entered 'None (0)'	System	19 Aug 2020 00:06:19

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:56', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2ed3b29e-4ff0-4a93-8a61-4094a8866077'	System	19 Aug 2020 00:06:19
User entered 'None (0)'	System	19 Aug 2020 00:06:19

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:59', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2ed3b29e-4ff0-4a93-8a61-4094a8866077'	System	19 Aug 2020 00:06:19
User entered 'None (0)'	System	19 Aug 2020 00:06:19

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:06:01', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2ed3b29e-4ff0-4a93-8a61-4094a8866077'	System	19 Aug 2020 00:06:19
User entered 'None (0)'	System	19 Aug 2020 00:06:19

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:06:03', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2ed3b29e-4ff0-4a93-8a61-4094a8866077'	System	19 Aug 2020 00:06:19
User entered 'None (0)'	System	19 Aug 2020 00:06:19

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:06:14', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2ed3b29e-4ff0-4a93-8a61-4094a8866077'	System	19 Aug 2020 00:06:19
User entered 'No (N)'	System	19 Aug 2020 00:06:19

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:06:17', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2ed3b29e-4ff0-4a93-8a61-4094a8866077'	System	19 Aug 2020 00:06:19
User entered '18 Aug 2020 19:06'	System	19 Aug 2020 00:06:19

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 18:41'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 21:11'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 22:06'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 2'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:35:39', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '455c59bb-f4e4-4b4a-9a6f-7373ea095fbe'	System	20 Aug 2020 03:36:50
User entered 'None (0)'	System	20 Aug 2020 03:36:50

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:35:48', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '455c59bb-f4e4-4b4a-9a6f-7373ea095fbe'	System	20 Aug 2020 03:36:50
User entered 'No interference with activity (1)'	System	20 Aug 2020 03:36:50

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:35:57', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '455c59bb-f4e4-4b4a-9a6f-7373ea095fbe'	System	20 Aug 2020 03:36:50
User entered 'None (0)'	System	20 Aug 2020 03:36:50

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:36:04', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '455c59bb-f4e4-4b4a-9a6f-7373ea095fbe'	System	20 Aug 2020 03:36:50
User entered 'None (0)'	System	20 Aug 2020 03:36:50

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:36:28', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '455c59bb-f4e4-4b4a-9a6f-7373ea095fbe'	System	20 Aug 2020 03:36:50
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	20 Aug 2020 03:36:50

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:36:32', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '455c59bb-f4e4-4b4a-9a6f-7373ea095fbe'	System	20 Aug 2020 03:36:50
User entered 'None (0)'	System	20 Aug 2020 03:36:50

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:36:37', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '455c59bb-f4e4-4b4a-9a6f-7373ea095fbe'	System	20 Aug 2020 03:36:50
User entered 'No (N)'	System	20 Aug 2020 03:36:50

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:36:47', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '455c59bb-f4e4-4b4a-9a6f-7373ea095fbe'	System	20 Aug 2020 03:36:50
User entered '19 Aug 2020 22:36'	System	20 Aug 2020 03:36:50

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 3'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:42:38', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3787c56d-e714-4a3f-8e35-aa6d6929fc88'	System	21 Aug 2020 03:43:20
User entered 'None (0)'	System	21 Aug 2020 03:43:20

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:42:47', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3787c56d-e714-4a3f-8e35-aa6d6929fc88'	System	21 Aug 2020 03:43:20
User entered 'None (0)'	System	21 Aug 2020 03:43:20

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:42:52', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3787c56d-e714-4a3f-8e35-aa6d6929fc88'	System	21 Aug 2020 03:43:20
User entered 'None (0)'	System	21 Aug 2020 03:43:20

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:42:56', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3787c56d-e714-4a3f-8e35-aa6d6929fc88'	System	21 Aug 2020 03:43:20
User entered 'None (0)'	System	21 Aug 2020 03:43:20

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:43:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3787c56d-e714-4a3f-8e35-aa6d6929fc88'	System	21 Aug 2020 03:43:20
User entered 'None (0)'	System	21 Aug 2020 03:43:20

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:43:03', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3787c56d-e714-4a3f-8e35-aa6d6929fc88'	System	21 Aug 2020 03:43:20
User entered 'None (0)'	System	21 Aug 2020 03:43:20

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:43:07', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3787c56d-e714-4a3f-8e35-aa6d6929fc88'	System	21 Aug 2020 03:43:20
User entered 'No (N)'	System	21 Aug 2020 03:43:20

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:43:16', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3787c56d-e714-4a3f-8e35-aa6d6929fc88'	System	21 Aug 2020 03:43:20
User entered '20 Aug 2020 22:43'	System	21 Aug 2020 03:43:20

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 4'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:35', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '35c85e60-edd7-4d4c-bb4c-6925c2b33d01'	System	22 Aug 2020 12:21:01
User entered 'None (0)'	System	22 Aug 2020 12:21:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:38', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '35c85e60-edd7-4d4c-bb4c-6925c2b33d01'	System	22 Aug 2020 12:21:01
User entered 'None (0)'	System	22 Aug 2020 12:21:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:42', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '35c85e60-edd7-4d4c-bb4c-6925c2b33d01'	System	22 Aug 2020 12:21:01
User entered 'None (0)'	System	22 Aug 2020 12:21:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:45', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '35c85e60-edd7-4d4c-bb4c-6925c2b33d01'	System	22 Aug 2020 12:21:01
User entered 'None (0)'	System	22 Aug 2020 12:21:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:48', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '35c85e60-edd7-4d4c-bb4c-6925c2b33d01'	System	22 Aug 2020 12:21:01
User entered 'None (0)'	System	22 Aug 2020 12:21:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:51', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '35c85e60-edd7-4d4c-bb4c-6925c2b33d01'	System	22 Aug 2020 12:21:01
User entered 'None (0)'	System	22 Aug 2020 12:21:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:54', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '35c85e60-edd7-4d4c-bb4c-6925c2b33d01'	System	22 Aug 2020 12:21:01
User entered 'No (N)'	System	22 Aug 2020 12:21:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:58', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '35c85e60-edd7-4d4c-bb4c-6925c2b33d01'	System	22 Aug 2020 12:21:01
User entered '22 Aug 2020 07:20'	System	22 Aug 2020 12:21:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 5'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:48

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9ba3e8bd-9d21-4a59-ae82-862a988fd608'	System	23 Aug 2020 05:00:53
User entered 'None (0)'	System	23 Aug 2020 05:00:53

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:48

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:28', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9ba3e8bd-9d21-4a59-ae82-862a988fd608'	System	23 Aug 2020 05:00:53
User entered 'None (0)'	System	23 Aug 2020 05:00:53

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:31', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9ba3e8bd-9d21-4a59-ae82-862a988fd608'	System	23 Aug 2020 05:00:53
User entered 'None (0)'	System	23 Aug 2020 05:00:53

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:34', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9ba3e8bd-9d21-4a59-ae82-862a988fd608'	System	23 Aug 2020 05:00:53
User entered 'None (0)'	System	23 Aug 2020 05:00:53

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:38', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9ba3e8bd-9d21-4a59-ae82-862a988fd608'	System	23 Aug 2020 05:00:53
User entered 'None (0)'	System	23 Aug 2020 05:00:53

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:48

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:40', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9ba3e8bd-9d21-4a59-ae82-862a988fd608'	System	23 Aug 2020 05:00:53
User entered 'None (0)'	System	23 Aug 2020 05:00:53

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:44', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9ba3e8bd-9d21-4a59-ae82-862a988fd608'	System	23 Aug 2020 05:00:53
User entered 'No (N)'	System	23 Aug 2020 05:00:53

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:48

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:48', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9ba3e8bd-9d21-4a59-ae82-862a988fd608'	System	23 Aug 2020 05:00:53
User entered '23 Aug 2020 00:00'	System	23 Aug 2020 05:00:53

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 6'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T09:56:10', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5a31f7c1-7458-4a85-907f-8e8afb72668d'	System	24 Aug 2020 14:56:37
User entered 'None (0)'	System	24 Aug 2020 14:56:37

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T09:56:13', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5a31f7c1-7458-4a85-907f-8e8afb72668d'	System	24 Aug 2020 14:56:37
User entered 'None (0)'	System	24 Aug 2020 14:56:37

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T09:56:16', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5a31f7c1-7458-4a85-907f-8e8afb72668d'	System	24 Aug 2020 14:56:37
User entered 'None (0)'	System	24 Aug 2020 14:56:37

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T09:56:19', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5a31f7c1-7458-4a85-907f-8e8afb72668d' User entered 'None (0)'	System	24 Aug 2020 14:56:37
	System	24 Aug 2020 14:56:37

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T09:56:22', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5a31f7c1-7458-4a85-907f-8e8afb72668d'	System	24 Aug 2020 14:56:37
User entered 'None (0)'	System	24 Aug 2020 14:56:37

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T09:56:25', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5a31f7c1-7458-4a85-907f-8e8afb72668d' User entered 'None (0)'	System	24 Aug 2020 14:56:37
	System	24 Aug 2020 14:56:37

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T09:56:28', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5a31f7c1-7458-4a85-907f-8e8afb72668d'	System	24 Aug 2020 14:56:37
User entered 'No (N)'	System	24 Aug 2020 14:56:37

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T09:56:34', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5a31f7c1-7458-4a85-907f-8e8afb72668d'	System	24 Aug 2020 14:56:37
User entered '24 Aug 2020 09:56'	System	24 Aug 2020 14:56:37

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 7'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:55', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2e1da49c-36a7-436c-a4fa-194ebd4e0f3f'	System	25 Aug 2020 03:42:22
User entered 'None (0)'	System	25 Aug 2020 03:42:22

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:58', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2e1da49c-36a7-436c-a4fa-194ebd4e0f3f' User entered 'None (0)'	System	25 Aug 2020 03:42:22
	System	25 Aug 2020 03:42:22

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:42:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2e1da49c-36a7-436c-a4fa-194ebd4e0f3f' User entered 'None (0)'	System	25 Aug 2020 03:42:22
	System	25 Aug 2020 03:42:22

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:42:03', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2e1da49c-36a7-436c-a4fa-194ebd4e0f3f' User entered 'None (0)'	System	25 Aug 2020 03:42:22

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:42:06', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2e1da49c-36a7-436c-a4fa-194ebd4e0f3f'	System	25 Aug 2020 03:42:22
User entered 'None (0)'	System	25 Aug 2020 03:42:22

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:42:10', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2e1da49c-36a7-436c-a4fa-194ebd4e0f3f'	System	25 Aug 2020 03:42:22
User entered 'None (0)'	System	25 Aug 2020 03:42:22

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:42:18', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2e1da49c-36a7-436c-a4fa-194ebd4e0f3f'	System	25 Aug 2020 03:42:22
User entered 'No (N)'	System	25 Aug 2020 03:42:22

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:42:21', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2e1da49c-36a7-436c-a4fa-194ebd4e0f3f' User entered '24 Aug 2020 22:42'	System	25 Aug 2020 03:42:22

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 18:01:22

US3442031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 18:01:22

US3442031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 18:01:22

US3442031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 18:01:22

US3442031

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 18:01:27

US3442031

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:01:27

US3442031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 14:16:44

US3442031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 14:16:44

US3442031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Sep 2020 14:16:44

US3442031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 14:16:44

US3442031

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 14:16:50

US3442031

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 14:16:50

US3442031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:50:18

US3442031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:50:18

US3442031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Sep 2020 16:50:18

US3442031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:50:18

US3442031

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:50:25

US3442031

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:50:25

US3442031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:13:44

US3442031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:13:44

US3442031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:13:44

US3442031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	21 Sep 2020 17:13:44

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '10:17'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 10:17'	System	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.4' F	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

Pulse (xxx)

Audit	User	Time (GMT)
User entered '65'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '12'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '121'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '85'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '11:50'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:50'	System	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.3' F	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '71'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '12'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '116'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '82'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:19

US3442031

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:19

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '11:20'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:20'	System	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:50

US3442031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:50

US3442031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:25'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:50

US3442031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 10:25'	System	21 Sep 2020 17:15:50

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:25:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:16:06

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:48

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Melody Dufrene (b) (4)	21 Sep 2020 17:16:06

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:16:06

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:30'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:16:06

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 10:30'	System	21 Sep 2020 17:16:06

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:48

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Melody Dufrene (b) (4)	21 Sep 2020 17:16:06

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:16:06

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:16:06

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:16:06

US3442031

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:16:12

US3442031

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:16:12

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:58:42', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0e4275c7-856c-49d0-8cfd-c811c12c3abc'	System	21 Sep 2020 16:59:07
User entered 'Yes (Y)'	System	21 Sep 2020 16:59:07

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:58:53', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0e4275c7-856c-49d0-8cfd-c811c12c3abc' User entered '97.3'	System	21 Sep 2020 16:59:07

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:58:58', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0e4275c7-856c-49d0-8cfd-c811c12c3abc'	System	21 Sep 2020 16:59:07
User entered 'No (N)'	System	21 Sep 2020 16:59:07

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:59:05', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0e4275c7-856c-49d0-8cfd-c811c12c3abc'	System	21 Sep 2020 16:59:07
User entered '21 Sep 2020 11:59'	System	21 Sep 2020 16:59:07

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:40'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 14:10'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:47:09', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '536ba1c3-b20d-491a-9948-bdda3bd9a8b4'	System	22 Sep 2020 02:47:33
User entered 'Yes (Y)'	System	22 Sep 2020 02:47:33

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:47:19', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '536ba1c3-b20d-491a-9948-bdda3bd9a8b4'	System	22 Sep 2020 02:47:33
User entered '97.5'	System	22 Sep 2020 02:47:33

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:47:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '536ba1c3-b20d-491a-9948-bdda3bd9a8b4'	System	22 Sep 2020 02:47:33
User entered 'No (N)'	System	22 Sep 2020 02:47:33

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:47:31', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '536ba1c3-b20d-491a-9948-bdda3bd9a8b4'	System	22 Sep 2020 02:47:33
User entered '21 Sep 2020 21:47'	System	22 Sep 2020 02:47:33

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 15:05'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 2'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:40:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c312159-7ee8-4cb4-8b28-807dd1c3946a'	System	23 Sep 2020 03:41:01
User entered 'Yes (Y)'	System	23 Sep 2020 03:41:01

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:40:33', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c312159-7ee8-4cb4-8b28-807dd1c3946a'	System	23 Sep 2020 03:41:01
User entered '99.5'	System	23 Sep 2020 03:41:01

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:40:37', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c312159-7ee8-4cb4-8b28-807dd1c3946a'	System	23 Sep 2020 03:41:01
User entered 'Yes (Y)'	System	23 Sep 2020 03:41:01

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'med added. logs updated.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 06:00:09
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:40:46', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c312159-7ee8-4cb4-8b28-807dd1c3946a'	System	23 Sep 2020 03:41:01
User entered '1'	System	23 Sep 2020 03:41:01

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:40:46', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c312159-7ee8-4cb4-8b28-807dd1c3946a' User entered '0'	System	23 Sep 2020 03:41:01

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:40:57', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c312159-7ee8-4cb4-8b28-807dd1c3946a'	System	23 Sep 2020 03:41:01
User entered '22 Sep 2020 22:40'	System	23 Sep 2020 03:41:01

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 3'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:33:13', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7eee96a6-1de5-4793-ad55-6bb13f13fc2f'	System	24 Sep 2020 03:33:41
User entered 'Yes (Y)'	System	24 Sep 2020 03:33:41

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:33:20', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7eee96a6-1de5-4793-ad55-6bb13f13fc2f'	System	24 Sep 2020 03:33:41
User entered '99.5'	System	24 Sep 2020 03:33:41

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:33:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7eee96a6-1de5-4793-ad55-6bb13f13fc2f'	System	24 Sep 2020 03:33:41
User entered 'Yes (Y)'	System	24 Sep 2020 03:33:41

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'med added. logs updated.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 06:00:13
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:33:30', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7eee96a6-1de5-4793-ad55-6bb13f13fc2f' User entered '1'	System	24 Sep 2020 03:33:41
	System	24 Sep 2020 03:33:41
	System	24 Sep 2020 03:33:41

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:33:30', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7eee96a6-1de5-4793-ad55-6bb13f13fc2f' User entered '0'	System	24 Sep 2020 03:33:41
	System	24 Sep 2020 03:33:41

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:33:39', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7eee96a6-1de5-4793-ad55-6bb13f13fc2f' User entered '23 Sep 2020 22:33'	System	24 Sep 2020 03:33:41
	System	24 Sep 2020 03:33:41

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 4'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:26:13', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '8a65e276-ee3f-4f14-9ba2-4b382221e110'	System	25 Sep 2020 03:26:38
User entered 'Yes (Y)'	System	25 Sep 2020 03:26:38

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:26:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '8a65e276-ee3f-4f14-9ba2-4b382221e110'	System	25 Sep 2020 03:26:38
User entered '97.7'	System	25 Sep 2020 03:26:38

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:26:30', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '8a65e276-ee3f-4f14-9ba2-4b382221e110'	System	25 Sep 2020 03:26:38
User entered 'No (N)'	System	25 Sep 2020 03:26:38

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:26:35', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '8a65e276-ee3f-4f14-9ba2-4b382221e110'	System	25 Sep 2020 03:26:38
User entered '24 Sep 2020 22:26'	System	25 Sep 2020 03:26:38

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 5'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 6'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:10:40', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'ced9a78b-4c21-45f5-953c-118956917b36'	System	26 Sep 2020 17:10:56
User entered 'Yes (Y)'	System	26 Sep 2020 17:10:56

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:10:48', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'ced9a78b-4c21-45f5-953c-118956917b36' User entered '97.4'	System	26 Sep 2020 17:10:56
	System	26 Sep 2020 17:10:56

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:10:52', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'ced9a78b-4c21-45f5-953c-118956917b36'	System	26 Sep 2020 17:10:56
User entered 'No (N)'	System	26 Sep 2020 17:10:56

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:10:55', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'ced9a78b-4c21-45f5-953c-118956917b36'	System	26 Sep 2020 17:10:56
User entered '26 Sep 2020 12:10'	System	26 Sep 2020 17:10:56

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 7'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:52:21', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '93030341-dd52-4290-aa72-f5edbe9a50e0'	System	28 Sep 2020 12:52:37
User entered 'Yes (Y)'	System	28 Sep 2020 12:52:37

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:52:28', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '93030341-dd52-4290-aa72-f5edbe9a50e0'	System	28 Sep 2020 12:52:37
User entered '97.5'	System	28 Sep 2020 12:52:37

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:52:32', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '93030341-dd52-4290-aa72-f5edbe9a50e0'	System	28 Sep 2020 12:52:37
User entered 'No (N)'	System	28 Sep 2020 12:52:37

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:52:36', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '93030341-dd52-4290-aa72-f5edbe9a50e0' User entered '28 Sep 2020 07:52'	System	28 Sep 2020 12:52:37
	System	28 Sep 2020 12:52:37

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:59:15', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'cc6a3120-3fd7-47a0-97c8-a93dc96bf966'	System	21 Sep 2020 16:59:45
User entered 'None (1)'	System	21 Sep 2020 16:59:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:59:18', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'cc6a3120-3fd7-47a0-97c8-a93dc96bf966'	System	21 Sep 2020 16:59:45
User entered 'No (N)'	System	21 Sep 2020 16:59:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:59:26', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'cc6a3120-3fd7-47a0-97c8-a93dc96bf966'	System	21 Sep 2020 16:59:45
User entered 'No (N)'	System	21 Sep 2020 16:59:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:59:35', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'cc6a3120-3fd7-47a0-97c8-a93dc96bf966'	System	21 Sep 2020 16:59:45
User entered 'None (1)'	System	21 Sep 2020 16:59:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:59:42', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'cc6a3120-3fd7-47a0-97c8-a93dc96bf966'	System	21 Sep 2020 16:59:45
User entered '21 Sep 2020 11:59'	System	21 Sep 2020 16:59:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:40'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 14:10'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:47:58', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3489aaeb-abaa-43bb-bf99-1552f9be6149'	System	22 Sep 2020 02:48:45
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 02:48:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:48:02', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3489aaeb-abaa-43bb-bf99-1552f9be6149'	System	22 Sep 2020 02:48:45
User entered 'No (N)'	System	22 Sep 2020 02:48:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:48:30', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3489aaeb-abaa-43bb-bf99-1552f9be6149'	System	22 Sep 2020 02:48:45
User entered 'No (N)'	System	22 Sep 2020 02:48:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:48:38', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3489aaeb-abaa-43bb-bf99-1552f9be6149'	System	22 Sep 2020 02:48:45
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 02:48:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:48:43', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3489aaeb-abaa-43bb-bf99-1552f9be6149'	System	22 Sep 2020 02:48:45
User entered '21 Sep 2020 21:48'	System	22 Sep 2020 02:48:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 15:05'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 2'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:41:22', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '364e9022-0048-4861-bec9-42ac3ab70b07'	System	23 Sep 2020 03:41:52
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	23 Sep 2020 03:41:52

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:41:27', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '364e9022-0048-4861-bec9-42ac3ab70b07'	System	23 Sep 2020 03:41:52
User entered 'No (N)'	System	23 Sep 2020 03:41:52

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:41:33', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '364e9022-0048-4861-bec9-42ac3ab70b07'	System	23 Sep 2020 03:41:52
User entered 'No (N)'	System	23 Sep 2020 03:41:52

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:41:46', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '364e9022-0048-4861-bec9-42ac3ab70b07'	System	23 Sep 2020 03:41:52
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 03:41:52

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:41:50', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '364e9022-0048-4861-bec9-42ac3ab70b07'	System	23 Sep 2020 03:41:52
User entered '22 Sep 2020 22:41'	System	23 Sep 2020 03:41:52

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 3'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:33:50', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0d63097e-dcfb-498d-b589-b84542a6f30b'	System	24 Sep 2020 03:34:35
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	24 Sep 2020 03:34:35

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:33:55', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0d63097e-dcfb-498d-b589-b84542a6f30b'	System	24 Sep 2020 03:34:35
User entered 'No (N)'	System	24 Sep 2020 03:34:35

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:34:07', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0d63097e-dcfb-498d-b589-b84542a6f30b'	System	24 Sep 2020 03:34:35
User entered 'No (N)'	System	24 Sep 2020 03:34:35

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:34:23', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0d63097e-dcfb-498d-b589-b84542a6f30b'	System	24 Sep 2020 03:34:35
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 03:34:35

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:34:31', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0d63097e-dcfb-498d-b589-b84542a6f30b'	System	24 Sep 2020 03:34:35
User entered '23 Sep 2020 22:34'	System	24 Sep 2020 03:34:35

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 4'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:26:46', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '680f6691-6619-4f9f-9f03-eaa9832b3fa7'	System	25 Sep 2020 03:27:10
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 03:27:10

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:26:51', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '680f6691-6619-4f9f-9f03-eaa9832b3fa7'	System	25 Sep 2020 03:27:10
User entered 'No (N)'	System	25 Sep 2020 03:27:10

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:26:55', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '680f6691-6619-4f9f-9f03-eea9832b3fa7'	System	25 Sep 2020 03:27:10
User entered 'No (N)'	System	25 Sep 2020 03:27:10

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:01', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '680f6691-6619-4f9f-9f03-eaa9832b3fa7'	System	25 Sep 2020 03:27:10
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 03:27:10

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:05', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '680f6691-6619-4f9f-9f03-aaa9832b3fa7'	System	25 Sep 2020 03:27:10
User entered '24 Sep 2020 22:27'	System	25 Sep 2020 03:27:10

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 5'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 6'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:02', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'b239fe1a-7b73-4aa5-abd5-11ea21cf3725'	System	26 Sep 2020 17:11:17
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 17:11:17

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:05', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'b239fe1a-7b73-4aa5-abd5-11ea21cf3725'	System	26 Sep 2020 17:11:17
User entered 'No (N)'	System	26 Sep 2020 17:11:17

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:08', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'b239fe1a-7b73-4aa5-abd5-11ea21cf3725'	System	26 Sep 2020 17:11:17
User entered 'No (N)'	System	26 Sep 2020 17:11:17

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:12', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'b239fe1a-7b73-4aa5-abd5-11ea21cf3725'	System	26 Sep 2020 17:11:17
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 17:11:17

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:15', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'b239fe1a-7b73-4aa5-abd5-11ea21cf3725'	System	26 Sep 2020 17:11:17
User entered '26 Sep 2020 12:11'	System	26 Sep 2020 17:11:17

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 7'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:52:41', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '399dddf8-9982-4585-b935-94fa99921070'	System	28 Sep 2020 12:52:59
User entered 'None (1)'	System	28 Sep 2020 12:52:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:52:45', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '399dddf8-9982-4585-b935-94fa99921070'	System	28 Sep 2020 12:52:59
User entered 'No (N)'	System	28 Sep 2020 12:52:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:52:48', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '399dddf8-9982-4585-b935-94fa99921070'	System	28 Sep 2020 12:52:59
User entered 'No (N)'	System	28 Sep 2020 12:52:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:52:53', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '399dddf8-9982-4585-b935-94fa99921070'	System	28 Sep 2020 12:52:59
User entered 'None (1)'	System	28 Sep 2020 12:52:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:52:55', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '399dddf8-9982-4585-b935-94fa99921070' User entered '28 Sep 2020 07:52'	System	28 Sep 2020 12:52:59
	System	28 Sep 2020 12:52:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:59:52', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'df5485b9-bc47-43f2-b883-0cc05c0ccb39'	System	21 Sep 2020 17:00:20
User entered 'None (0)'	System	21 Sep 2020 17:00:20

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:59:55', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'df5485b9-bc47-43f2-b883-0cc05c0ccb39'	System	21 Sep 2020 17:00:20
User entered 'None (0)'	System	21 Sep 2020 17:00:20

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:59:58', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'df5485b9-bc47-43f2-b883-0cc05c0ccb39'	System	21 Sep 2020 17:00:20
User entered 'None (0)'	System	21 Sep 2020 17:00:20

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T12:00:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'df5485b9-bc47-43f2-b883-0cc05c0ccb39'	System	21 Sep 2020 17:00:20
User entered 'None (0)'	System	21 Sep 2020 17:00:20

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T12:00:03', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'df5485b9-bc47-43f2-b883-0cc05c0ccb39'	System	21 Sep 2020 17:00:20
User entered 'None (0)'	System	21 Sep 2020 17:00:20

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T12:00:06', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'df5485b9-bc47-43f2-b883-0cc05c0ccb39'	System	21 Sep 2020 17:00:20
User entered 'None (0)'	System	21 Sep 2020 17:00:20

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T12:00:09', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'df5485b9-bc47-43f2-b883-0cc05c0ccb39'	System	21 Sep 2020 17:00:20
User entered 'No (N)'	System	21 Sep 2020 17:00:20

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T12:00:14', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'df5485b9-bc47-43f2-b883-0cc05c0ccb39'	System	21 Sep 2020 17:00:20
User entered '21 Sep 2020 12:00'	System	21 Sep 2020 17:00:20

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:40'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 14:10'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:48:52', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '13a72f1a-588d-42d3-874e-3375fb1c0519'	System	22 Sep 2020 02:49:27
User entered 'None (0)'	System	22 Sep 2020 02:49:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:48:58', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '13a72f1a-588d-42d3-874e-3375fb1c0519'	System	22 Sep 2020 02:49:27
User entered 'None (0)'	System	22 Sep 2020 02:49:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:49:07', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '13a72f1a-588d-42d3-874e-3375fb1c0519'	System	22 Sep 2020 02:49:27
User entered 'None (0)'	System	22 Sep 2020 02:49:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:49:10', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '13a72f1a-588d-42d3-874e-3375fb1c0519'	System	22 Sep 2020 02:49:27
User entered 'None (0)'	System	22 Sep 2020 02:49:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:49:13', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '13a72f1a-588d-42d3-874e-3375fb1c0519'	System	22 Sep 2020 02:49:27
User entered 'None (0)'	System	22 Sep 2020 02:49:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:49:17', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '13a72f1a-588d-42d3-874e-3375fb1c0519'	System	22 Sep 2020 02:49:27
User entered 'None (0)'	System	22 Sep 2020 02:49:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:49:20', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '13a72f1a-588d-42d3-874e-3375fb1c0519'	System	22 Sep 2020 02:49:27
User entered 'No (N)'	System	22 Sep 2020 02:49:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:49:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '13a72f1a-588d-42d3-874e-3375fb1c0519'	System	22 Sep 2020 02:49:27
User entered '21 Sep 2020 21:49'	System	22 Sep 2020 02:49:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 15:05'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 2'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:42:11', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c85fefaa-61da-4c78-823b-bf63f09e9797'	System	23 Sep 2020 03:43:00
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	23 Sep 2020 03:43:00

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:42:16', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c85fefaa-61da-4c78-823b-bf63f09e9797'	System	23 Sep 2020 03:43:00
User entered 'Some interference with activity (2)'	System	23 Sep 2020 03:43:00

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:42:22', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c85fefaa-61da-4c78-823b-bf63f09e9797'	System	23 Sep 2020 03:43:00
User entered 'Some interference with activity (2)'	System	23 Sep 2020 03:43:00

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:42:31', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c85fefaa-61da-4c78-823b-bf63f09e9797'	System	23 Sep 2020 03:43:00
User entered 'No interference with activity (1)'	System	23 Sep 2020 03:43:00

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:42:40', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c85fefaa-61da-4c78-823b-bf63f09e9797'	System	23 Sep 2020 03:43:00
User entered 'None (0)'	System	23 Sep 2020 03:43:00

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:42:45', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c85fefaa-61da-4c78-823b-bf63f09e9797'	System	23 Sep 2020 03:43:00
User entered 'None (0)'	System	23 Sep 2020 03:43:00

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:42:50', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c85fefaa-61da-4c78-823b-bf63f09e9797'	System	23 Sep 2020 03:43:00
User entered 'No (N)'	System	23 Sep 2020 03:43:00

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:42:56', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c85fefaa-61da-4c78-823b-bf63f09e9797'	System	23 Sep 2020 03:43:00
User entered '22 Sep 2020 22:42'	System	23 Sep 2020 03:43:00

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 3'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:34:40', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c3056c39-7d9c-4f90-9e72-72b3422299ba'	System	24 Sep 2020 03:35:27
User entered 'None (0)'	System	24 Sep 2020 03:35:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:34:50', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c3056c39-7d9c-4f90-9e72-72b3422299ba'	System	24 Sep 2020 03:35:27
User entered 'Significant; prevents daily activity (3)'	System	24 Sep 2020 03:35:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:35:02', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c3056c39-7d9c-4f90-9e72-72b3422299ba'	System	24 Sep 2020 03:35:27
User entered 'Some interference with activity (2)'	System	24 Sep 2020 03:35:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:35:07', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c3056c39-7d9c-4f90-9e72-72b3422299ba'	System	24 Sep 2020 03:35:27
User entered 'Some interference with activity (2)'	System	24 Sep 2020 03:35:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:35:12', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c3056c39-7d9c-4f90-9e72-72b3422299ba'	System	24 Sep 2020 03:35:27
User entered 'None (0)'	System	24 Sep 2020 03:35:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:35:16', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c3056c39-7d9c-4f90-9e72-72b3422299ba' User entered 'None (0)'	System	24 Sep 2020 03:35:27
	System	24 Sep 2020 03:35:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:35:20', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c3056c39-7d9c-4f90-9e72-72b3422299ba'	System	24 Sep 2020 03:35:27
User entered 'No (N)'	System	24 Sep 2020 03:35:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:35:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c3056c39-7d9c-4f90-9e72-72b3422299ba' User entered '23 Sep 2020 22:35'	System	24 Sep 2020 03:35:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 4'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:16', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c6b7a18-1193-4844-8d4e-9fc71cd08adb' User entered 'None (0)'	System	25 Sep 2020 03:27:46
	System	25 Sep 2020 03:27:46

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:25', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c6b7a18-1193-4844-8d4e-9fc71cd08adb'	System	25 Sep 2020 03:27:46
User entered 'No interference with activity (1)'	System	25 Sep 2020 03:27:46

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:28', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c6b7a18-1193-4844-8d4e-9fc71cd08adb'	System	25 Sep 2020 03:27:46
User entered 'No interference with activity (1)'	System	25 Sep 2020 03:27:46

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:32', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c6b7a18-1193-4844-8d4e-9fc71cd08adb'	System	25 Sep 2020 03:27:46
User entered 'No interference with activity (1)'	System	25 Sep 2020 03:27:46

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:35', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c6b7a18-1193-4844-8d4e-9fc71cd08adb' User entered 'None (0)'	System	25 Sep 2020 03:27:46
	System	25 Sep 2020 03:27:46

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:38', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c6b7a18-1193-4844-8d4e-9fc71cd08adb' User entered 'None (0)'	System	25 Sep 2020 03:27:46
	System	25 Sep 2020 03:27:46

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:41', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c6b7a18-1193-4844-8d4e-9fc71cd08adb' User entered 'No (N)'	System	25 Sep 2020 03:27:46

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:44', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c6b7a18-1193-4844-8d4e-9fc71cd08adb' User entered '24 Sep 2020 22:27'	System	25 Sep 2020 03:27:46

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 5'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 6'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:18', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5270c9f8-1f8e-4b17-98e6-d9b7d7913b2e'	System	26 Sep 2020 17:11:42
User entered 'None (0)'	System	26 Sep 2020 17:11:42

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:21', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5270c9f8-1f8e-4b17-98e6-d9b7d7913b2e'	System	26 Sep 2020 17:11:42
User entered 'No interference with activity (1)'	System	26 Sep 2020 17:11:42

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:25', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5270c9f8-1f8e-4b17-98e6-d9b7d7913b2e'	System	26 Sep 2020 17:11:42
User entered 'No interference with activity (1)'	System	26 Sep 2020 17:11:42

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:28', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5270c9f8-1f8e-4b17-98e6-d9b7d7913b2e' User entered 'None (0)'	System	26 Sep 2020 17:11:42
	System	26 Sep 2020 17:11:42

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:30', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5270c9f8-1f8e-4b17-98e6-d9b7d7913b2e'	System	26 Sep 2020 17:11:42
User entered 'None (0)'	System	26 Sep 2020 17:11:42

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:32', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5270c9f8-1f8e-4b17-98e6-d9b7d7913b2e' User entered 'None (0)'	System	26 Sep 2020 17:11:42
	System	26 Sep 2020 17:11:42

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:35', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5270c9f8-1f8e-4b17-98e6-d9b7d7913b2e'	System	26 Sep 2020 17:11:42
User entered 'No (N)'	System	26 Sep 2020 17:11:42

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:37', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5270c9f8-1f8e-4b17-98e6-d9b7d7913b2e'	System	26 Sep 2020 17:11:42
User entered '26 Sep 2020 12:11'	System	26 Sep 2020 17:11:42

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 7'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:53:01', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f80e09a4-cbbf-41e1-a4da-f84f934b734f'	System	28 Sep 2020 12:53:26
User entered 'None (0)'	System	28 Sep 2020 12:53:26

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:53:06', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f80e09a4-cbbf-41e1-a4da-f84f934b734f' User entered 'None (0)'	System	28 Sep 2020 12:53:26
	System	28 Sep 2020 12:53:26

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:53:10', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f80e09a4-cbbf-41e1-a4da-f84f934b734f'	System	28 Sep 2020 12:53:26
User entered 'None (0)'	System	28 Sep 2020 12:53:26

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:53:13', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f80e09a4-cbbf-41e1-a4da-f84f934b734f' User entered 'None (0)'	System	28 Sep 2020 12:53:26

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:53:15', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f80e09a4-cbbf-41e1-a4da-f84f934b734f'	System	28 Sep 2020 12:53:26
User entered 'None (0)'	System	28 Sep 2020 12:53:26

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:53:18', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f80e09a4-cbbf-41e1-a4da-f84f934b734f' User entered 'None (0)'	System	28 Sep 2020 12:53:26
	System	28 Sep 2020 12:53:26

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:53:21', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f80e09a4-cbbf-41e1-a4da-f84f934b734f' User entered 'No (N)'	System	28 Sep 2020 12:53:26

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:53:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f80e09a4-cbbf-41e1-a4da-f84f934b734f' User entered '28 Sep 2020 07:53'	System	28 Sep 2020 12:53:26
	System	28 Sep 2020 12:53:26

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:52:58

US3442031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 15:52:58

US3442031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Sep 2020 15:52:58

US3442031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:52:58

US3442031

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:53:03

US3442031

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:53:03

US3442031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 23:18:40

US3442031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 23:18:40

US3442031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[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 23:18:40

US3442031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:18:40

US3442031

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 23:18:45

US3442031

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 23:18:45

US3442031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 21:19:09

US3442031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 21:19:09

US3442031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 21:19:09

US3442031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 21:19:09

US3442031

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 21:19:15

US3442031

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 21:19:15

US3442031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 15:19:29

US3442031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 15:19:29

US3442031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

[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 15:19:29

US3442031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	16 Oct 2020 15:19:29

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 15:19:51

US3442031

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 15:19:51

US3442031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 15:20:04

US3442031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 15:20:04

US3442031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:52'	(b) (4), (b) (6)	16 Oct 2020 15:20:04

US3442031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 09:52'	System	16 Oct 2020 15:20:04

US3442031

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 15:20:10

US3442031

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 15:20:10

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 64'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-10-18T16:38:35', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0177fd21-15b9-4c63-b48e-dca93cb6e435'	System	18 Oct 2020 21:38:54
User entered 'No (N)'	System	18 Oct 2020 21:38:54

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-10-18T16:38:43', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0177fd21-15b9-4c63-b48e-dca93cb6e435'	System	18 Oct 2020 21:38:54
User entered 'No (N)'	System	18 Oct 2020 21:38:54

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-10-18T16:38:51', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0177fd21-15b9-4c63-b48e-dca93cb6e435' User entered '18 Oct 2020 16:38:51'	System	18 Oct 2020 21:38:54
	System	18 Oct 2020 21:38:54

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered '18 Oct 2020 00:01'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered '22 Oct 2020 23:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 71'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-10-27T12:00:47', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7d3da2b5-77d8-461c-9f9e-7eb3bae531c5'	System	27 Oct 2020 17:02:00
User entered 'No (N)'	System	27 Oct 2020 17:02:00

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-10-27T12:00:54', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7d3da2b5-77d8-461c-9f9e-7eb3bae531c5'	System	27 Oct 2020 17:02:00
User entered 'No (N)'	System	27 Oct 2020 17:02:00

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-10-27T12:01:01', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7d3da2b5-77d8-461c-9f9e-7eb3bae531c5' User entered '27 Oct 2020 12:01:01'	System	27 Oct 2020 17:02:00
	System	27 Oct 2020 17:02:00

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered '25 Oct 2020 00:01'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered '29 Oct 2020 23:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 78'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-11-01T10:57:10', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '51f0e67e-2e67-4ce1-9887-6082ed717e86'	System	01 Nov 2020 16:57:36
User entered 'No (N)'	System	01 Nov 2020 16:57:36

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-11-01T10:57:25', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '51f0e67e-2e67-4ce1-9887-6082ed717e86'	System	01 Nov 2020 16:57:36
User entered 'No (N)'	System	01 Nov 2020 16:57:36

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-11-01T10:57:30', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '51f0e67e-2e67-4ce1-9887-6082ed717e86' User entered '01 Nov 2020 10:57:30'	System	01 Nov 2020 16:57:36
	System	01 Nov 2020 16:57:36

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered '01 Nov 2020 00:01'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered '05 Nov 2020 23:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 92'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-11-17T12:00:38', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'a949e428-d1ca-4234-861f-ff5d97bad71b'	System	17 Nov 2020 18:00:59
User entered 'No (N)'	System	17 Nov 2020 18:00:59

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-11-17T12:00:47', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'a949e428-d1ca-4234-861f-ff5d97bad71b'	System	17 Nov 2020 18:00:59
User entered 'No (N)'	System	17 Nov 2020 18:00:59

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-11-17T12:00:52', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'a949e428-d1ca-4234-861f-ff5d97bad71b'	System	17 Nov 2020 18:00:59
User entered '17 Nov 2020 12:00:52'	System	17 Nov 2020 18:00:59

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered '15 Nov 2020 00:01'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 23:23:35
User entered '19 Nov 2020 23:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '15 Oct 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '19 Oct 2020 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '22 Oct 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '26 Oct 2020 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '29 Oct 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '02 Nov 2020 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '05 Nov 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '09 Nov 2020 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '12 Nov 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '16 Nov 2020 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:25:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:28:56
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:49:48

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site warmth, LLT: Injection site warmth - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:24:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:24:42
Data point term sent to Coder	System	28 Aug 2020 19:51:40
User entered 'HEAT AT INJECTION SITE'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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	28 Aug 2020 19:51:48
User entered empty; reason for change Data Entry Error	Melody Dufrene (b) (4)	28 Aug 2020 19:51:48
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	28 Aug 2020 19:51:21
User entered '00:00'	Melody Dufrene (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 19:51:48
User entered '26 Aug 2020 00:00'	System	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	28 Aug 2020 19:52:09
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).		28 Aug 2020 19:52:09
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	28 Aug 2020 19:51:21
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Melody Dufrene (b) (4)	28 Aug 2020 19:52:09
User entered 'No (N)'	Melody Dufrene (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 20:07:07
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	John Villegas (b) (4)	18 Nov 2020 22:01:58
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'Per Sub-I, heat at injection site is a causality to IP, not to the study procedure itself' (Site from DM).	John Villegas (b) (4)	18 Nov 2020 22:01:52
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:11:28
User entered 'Not Applicable (NOT APPLICABLE)'	Melody Dufrene (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[None](#)

Audit	User	Time (GMT)
User entered '1'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 20:02:26
User closed query 'Per DM CLR: Please review if this is a lymphadenopathy. If so, please update term to lymphadenopathy and include the location (eg, injection site lymphadenopathy, etc). Else, provide comment in query response to confirm this is not lymphadenopathy.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 20:02:16
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Vaccination site reactions, PT: Vaccination site lymphadenopathy, LLT: Vaccination site lymphadenopathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 13:02:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 13:02:32
Data point term sent to Coder	System	04 Nov 2020 21:55:52
Query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 21:55:45
Coding entries removed.	(b) (4), (b) (6)	04 Nov 2020 21:55:18
User entered 'SWOLLEN LYMPH NODES RIGHT AXILLA- ipsilateral to vaccination site' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 21:55:18
User opened query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 02:20:23

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review if this is a lymphadenopathy. If so, please update term to lymphadenopathy and include the location (eg, injection site lymphadenopathy, etc). Else, provide comment in query response to confirm this is not lymphadenopathy.' answered with 'correct as entered. subject does not have lymphadenopathy.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:35:55
User opened query 'Per DM CLR: Please review if this is a lymphadenopathy. If so, please update term to lymphadenopathy and include the location (eg, injection site lymphadenopathy, etc). Else, provide comment in query response to confirm this is not lymphadenopathy.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:52:07
User closed query 'Per DM CLR: Please specify the location of SWOLLEN LYMPH NODES (e.g., Both Axillas, Right Groin, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 12:17:06
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Axillary lymph nodes enlarged - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 20:55:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 20:55:49
Data point term sent to Coder	System	08 Oct 2020 14:17:35
Query 'Per DM CLR: Please specify the location of SWOLLEN LYMPH NODES (e.g., Both Axillas, Right Groin, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:16:58
Coding entries removed.	(b) (4), (b) (6)	08 Oct 2020 14:16:48
User entered 'SWOLLEN LYMPH NODES right axilla' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:16:48

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify the location of SWOLLEN LYMPH NODES (e.g., Both Axillas, Right Groin, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:37:38
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Swollen lymph nodes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 19:55:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 19:55:46
Data point term sent to Coder	System	28 Aug 2020 19:54:45
User entered 'SWOLLEN LYMPH NODES'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 19:55:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 19:55:09
User entered 'Related (RELATED)' reason for change: Data Entry Error	Melody Dufrene (b) (4)	28 Aug 2020 19:55:09
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 19:54:32
User entered empty.	Melody Dufrene (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 19:55:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 19:55:09
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Melody Dufrene (b) (4)	28 Aug 2020 19:55:09
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 19:54:32
User entered empty.	Melody Dufrene (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 19:55:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 19:55:09
User entered 'None (NONE)' reason for change: Data Entry Error	Melody Dufrene (b) (4)	28 Aug 2020 19:55:09
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 19:54:32
User entered empty.	Melody Dufrene (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[None](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:16:48
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 12:17:14
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:17:05
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:16:48
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 02:32:03
User entered '1'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 19:55:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 19:55:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Melody Dufrene (b) (4)	28 Aug 2020 19:55:15
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 19:54:32
User entered empty.	Melody Dufrene (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:51:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered 'USA-US017-2020-mRNA-1273-P301000003'	System	09 Nov 2020 18:01:41
User entered 'New'	(b) (4), (b) (6)	09 Nov 2020 18:01:41

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:27:15
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis leg - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 00:08:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 00:08:36
Data point term sent to Coder	System	13 Nov 2020 17:36:06
DataPoint Un-verified.	Alma Guel (b) (4)	13 Nov 2020 17:35:43
Coding entries removed.	Alma Guel (b) (4)	13 Nov 2020 17:35:43
User entered 'DEEP VEIN THROMBOSIS (Left Leg)' reason for change: Data Entry Error	Alma Guel (b) (4)	13 Nov 2020 17:35:43
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:51:27
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:26:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:26:33
Data point term sent to Coder	System	06 Nov 2020 21:25:16
User entered 'Deep Vein Thrombosis'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:53:45
User entered 'Yes (Y)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:53:46
User entered 'No (N)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:53:48
User entered 'No (N)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:53:52
User entered '3 Nov 2020'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:53:53
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:53:55
User entered 'No (N)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:53:57
User entered '4 Nov 2020'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:54:00
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 21:26:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 21:26:19
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Nov 2020 21:26:19
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 21:25:01
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:54:03
User entered 'Yes (Y)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:54:05
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:54:07
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:54:16
User entered '1'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:54:28
User entered '3 Nov 2020'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:54:46
User entered '4 Nov 2020'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:54:48
User entered 'No (N)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:54:50
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:54:51
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:54:53
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:54:54
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:54:56
User entered 'Not Related (NOT RELATED)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:54:57
User entered 'Not Related (NOT RELATED)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:54:59
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:24:27
User closed query 'Subject is received medications after the diagnosis. Please check the concomitant Medication option. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:23:52
Query 'Subject is received medications after the diagnosis. Please check the concomitant Medication option. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	13 Nov 2020 17:06:18
User entered '0' reason for change: Data Entry Error	Alma Guel (b) (4)	13 Nov 2020 17:06:10
User opened query 'Subject is received medications after the diagnosis. Please check the concomitant Medication option. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 18:02:49
User entered '1'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:24:45
User entered '1' reason for change: Data Entry Error	Alma Guel (b) (4)	13 Nov 2020 17:06:10
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:24:48
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:02:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:02:56
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:03
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	06 Nov 2020 21:26:01
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	06 Nov 2020 21:26:01
User entered 'Subject hospitalized overnight for deep Alma Guel vein thrombosis. Subject was released and medical records have been requested.' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 21:26:01
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	06 Nov 2020 21:25:01
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:02:15
User entered 'USA-US017-2020-mRNA-1273-P301000003'	(b) (4), (b) (6)	09 Nov 2020 18:02:10

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:11
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:44:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:44:32
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:29:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:29:24
Data point term sent to Coder	System	06 Nov 2020 21:28:22
User entered 'Pulmonary Embolism'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:13
User entered 'Yes (Y)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:15
User entered 'No (N)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:17
User entered 'No (N)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:19
User entered '3 Nov 2020'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:21
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:23
User entered 'No (N)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:25
User entered '4 Nov 2020'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:28
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:29
User entered 'Grade 3/Severe (Grade 3/Severe)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:31
User entered 'Yes (Y)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:34
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:36
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:38
User entered '1'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:40
User entered '3 Nov 2020'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:41
User entered '4 Nov 2020'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:43
User entered 'No (N)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:45
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:47
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:49
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:51
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:53
User entered 'Not Related (NOT RELATED)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:54
User entered 'Not Related (NOT RELATED)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:56
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:26:56
User closed query 'Subject is taking medications related to the condition. Please check the option of concomitant medication. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:26:46
Query 'Subject is taking medications related to the condition. Please check the option of concomitant medication. ' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	13 Nov 2020 17:34:55
User entered '0' reason for change: Data Entry Error	Alma Guel (b) (4)	13 Nov 2020 17:34:44
User opened query 'Subject is taking medications related to the condition. Please check the option of concomitant medication. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 18:04:42
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 18:04:00
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:03:58
User entered '1'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:26:58
User entered '1' reason for change: Data Entry Error	Alma Guel (b) (4)	13 Nov 2020 17:34:44
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:27:01
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:04:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:04:50
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Was the subject tested for COVID-19 while hospitalized? If yes, please provide results. ' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 17:44:53
User opened query 'PV Query: Please provide clinical work-ups for thrombophilia.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 17:40:33
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 17:39:39
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 17:39:29
User opened query 'PV Query: Please provide treatment given for the events 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)	13 Nov 2020 17:38:37
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:04:52
User entered 'SUBJECT HOSPITALIZED OVERNIGHT FOR Pulmonary Embolism. SUBJECT WAS RELEASED AND MEDICAL RECORDS HAVE BEEN REQUESTED'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Calf pain - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 16:26:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 16:26:51
Data point term sent to Coder	System	14 Nov 2020 16:26:15
User entered 'Left Calf Pain'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 16:27:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Nov 2020 16:27:13
User entered 'No (N)' reason for change: Data Entry Error	Alma Guel (b) (4)	14 Nov 2020 16:27:13
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 16:25:23
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '1 Nov 2020'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:15:57
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' answered with 'updated' (Site from DM).	Alma Guel (b) (4)	23 Nov 2020 20:57:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alma Guel (b) (4)	23 Nov 2020 20:57:33
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:10:29
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Relationship to Study Procedure](#)

Audit	User		Time (GMT)
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alma Guel	(b) (4)	23 Nov 2020 20:57:33
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel	(b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[None](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Nov 2020 16:25:23

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 08:24:59
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 21:46:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder Query '	Coder Import (b) (4)	20 Nov 2020 21:46:03
	System	20 Nov 2020 21:45:09
	Coder Import (b) (4)	20 Nov 2020 21:45:07
	(b) (4)	
For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc).' canceled (Site from System).		
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 21:45:05
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 21:45:05
User opened query '	(b) (4)	
	Coder Import (b) (4)	16 Nov 2020 12:58:43
	(b) (4)	
For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc).' (Site from System).		

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 16:29:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 16:29:51
Data point term sent to Coder	System	14 Nov 2020 16:29:15
User entered 'Chest Pain'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '4 Nov 2020'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Severity](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 16:28:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Nov 2020 16:28:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Alma Guel (b) (4)	14 Nov 2020 16:28:52
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 16:28:45
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:16:19
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' answered with 'updated' (Site from DM).	Alma Guel (b) (4)	23 Nov 2020 20:59:17
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alma Guel (b) (4)	23 Nov 2020 20:59:08
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:10:46
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Relationship to Study Procedure](#)

Audit	User		Time (GMT)
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alma Guel	(b) (4)	23 Nov 2020 20:59:08
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel	(b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[None](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Nov 2020 16:28:45

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 16:34:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 16:34:51
Data point term sent to Coder	System	14 Nov 2020 16:34:18
User entered 'Shortness of breath'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '4 Nov 2020'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:16:30
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' answered with 'updated' (Site from DM).	Alma Guel (b) (4)	23 Nov 2020 20:58:27
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alma Guel (b) (4)	23 Nov 2020 20:58:21
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:11:05
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Relationship to Study Procedure](#)

Audit	User		Time (GMT)
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alma Guel	(b) (4)	23 Nov 2020 20:58:21
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel	(b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: Action taken with IP should be recorded as NOT APPLICABLE if the AE started after the second dose. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:16:32
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Alma Guel (b) (4)	23 Nov 2020 20:58:48
Query 'Per CDM: Action taken with IP should be recorded as NOT APPLICABLE if the AE started after the second dose. Please update accordingly. ' answered with 'updated' (Site from DM).	Alma Guel (b) (4)	23 Nov 2020 20:58:36
User opened query 'Per CDM: Action taken with IP should be recorded as NOT APPLICABLE if the AE started after the second dose. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 10:52:56
User entered 'None (NONE)'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[None](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 22:58:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 22:58:01
Data point term sent to Coder	System	19 Nov 2020 22:57:01
User entered 'Nausea'	Tisha Davis (b) (4)	19 Nov 2020 22:56:44
	(b) (4)	

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	19 Nov 2020 22:57:04
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).		19 Nov 2020 22:57:04
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	19 Nov 2020 22:56:44
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Tisha Davis (b) (4)	19 Nov 2020 22:57:04
User entered 'No (N)'	Tisha Davis (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[None](#)

Audit	User	Time (GMT)
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Tisha Davis (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 23:14:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 23:14:50
Data point term sent to Coder	System	19 Nov 2020 22:59:07
User entered 'Vomiting'	Tisha Davis (b) (4)	19 Nov 2020 22:58:16
	(b) (4)	

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[None](#)

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Nov 2020 22:58:34
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Nov 2020 22:58:16
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Tisha Davis (b) (4)	19 Nov 2020 22:58:34
User entered '0'	(b) (4) Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Tisha Davis (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 22:58:16

US3442031

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 22:58:16

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:25:48

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

[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: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Sep 2020 14:22:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Sep 2020 14:22:43
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: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Sep 2020 14:21:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Sep 2020 14:21:29
Data point term sent to Coder Query 'CDM-Coding: The trade name protonix can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' canceled (Site from System).	System Coder Import (b) (4)	01 Sep 2020 14:21:20 01 Sep 2020 14:20:39
Data point term sent to Coder User entered 'PROTONIX (pantoprazole)' reason for change: Per Query Resolution	System (b) (4), (b) (6)	01 Sep 2020 14:20:18 01 Sep 2020 14:19:28
User opened query 'CDM-Coding: The trade name protonix can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' (Site from System).	Coder Import (b) (4)	01 Sep 2020 07:42:41
v6.020 DTW (1102)		
1896 of 2130		

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	25 Aug 2020 15:25:49
User entered 'PROTONIX'	Melody Dufrene (b) (4)	25 Aug 2020 15:25:37
	(b) (4)	

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'ACID REFLUX'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 17:38:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 17:38:46
Data point term sent to Coder	System	13 Nov 2020 17:38:07
Coding entries removed.	Alma Guel (b) (4)	13 Nov 2020 17:37:27
User entered 'Levothyroxine' reason for change: Data Entry Error	Alma Guel (b) (4)	13 Nov 2020 17:37:27
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 15:27:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 15:27:33
Data point term sent to Coder	System	25 Aug 2020 15:26:50
User entered 'SYNTHROID'	Melody Dufrene (b) (4)	25 Aug 2020 15:26:38
	(b) (4)	

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'HYPOTHYROIDISM'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: 'Dose unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please confirm if any other suitable predefined option is available under the data field 'Dose unit' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 04:26:01
Query 'Per CDM: 'Dose unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please confirm if any other suitable predefined option is available under the data field 'Dose unit' for this medication and update as required. Otherwise please provide explanation.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 21:03:05
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 21:02:58
User opened query 'Per CDM: 'Dose unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please confirm if any other suitable predefined option is available under the data field 'Dose unit' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 17:14:02
User entered 'Other (OTHER)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 21:02:58
User entered 'MCG'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:54:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:54:39
Data point term sent to Coder	System	25 Aug 2020 15:27:55
User entered 'AMITRIPTYLINE'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'ANXIETY'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 11:35:07
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition. Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'Medical History has been updated Data enter in error' (Site from DM).	John Villegas (b) (4)	01 Oct 2020 17:30:08
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 08:44:47
User entered 'UN UNK 2016'	Melody Dufrene (b) (4)	25 Aug 2020 15:27:34
	(b) (4)	

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 15:30:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 15:30:30
Data point term sent to Coder	System	25 Aug 2020 15:28:56
User entered 'SERTRALINE'	Melody Dufrene (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'ANXIETY'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 15:30:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 15:30:30
Data point term sent to Coder	System	25 Aug 2020 15:29:59
User entered 'ASA'	Melody Dufrene (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'CARDIAC PROPHYLAXIS'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

[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)	05 Oct 2020 23:23:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 23:23:32
Data point term sent to Coder	System	05 Oct 2020 23:22:12
User entered 'tylenol'	(b) (4), (b) (6)	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 20:03:43
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' answered with 'does not meet AE reporting Criteria.' (Site from DM).	John Villegas (b) (4)	13 Nov 2020 23:02:36
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 20:49:35
User entered 'injection site pain'	(b) (4), (b) (6)	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	(b) (4), (b) (6)	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '19 Aug 2020'	(b) (4), (b) (6)	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	(b) (4), (b) (6)	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 23:24:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 23:24:25
Data point term sent to Coder	System	05 Oct 2020 23:23:12
User entered 'zofran'	(b) (4), (b) (6)	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:08:34
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'AE log updated' (Site from DM).	Tisha Davis (b) (4)	19 Nov 2020 22:46:40
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 20:50:24
User entered 'nausea'	(b) (4), (b) (6)	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '8'	(b) (4), (b) (6)	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	(b) (4), (b) (6)	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

[Was this medication taken for solicited event?](#)

Audit	User		Time (GMT)
Query 'Per CDM re-query: The response indicates updated; However the response for the question 'Was this medication taken for solicited event?' is still Yes. As the event occurred outside the solicited period (after 7 days of dosing), please review the response and update as appropriate. ' answered with 'data updated' (Site from DM).	Alma Guel	(b) (4)	23 Nov 2020 20:56:40
User entered 'No (N)' reason for change: Data Entry Error	Alma Guel	(b) (4)	23 Nov 2020 20:56:32
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes, however, the medication was taken not within the solicited period for this subject. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)		23 Nov 2020 09:19:15
User opened query 'Per CDM re-query: The response indicates updated; However the response for the question 'Was this medication taken for solicited event?' is still Yes. As the event occurred outside the solicited period (after 7 days of dosing), please review the response and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)		23 Nov 2020 09:19:13
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes, however, the medication was taken not within the solicited period for this subject. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated per query' (Site from DM).	Tisha Davis	(b) (4)	19 Nov 2020 22:46:13
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes, however, the medication was taken not within the solicited period for this subject. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)		12 Nov 2020 20:50:39
User entered 'Yes (Y)'	(b) (4), (b) (6)		05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

[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)	05 Oct 2020 23:25:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 23:25:25
Data point term sent to Coder	System	05 Oct 2020 23:24:14
User entered 'tylenol'	(b) (4), (b) (6)	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the ELEVATED TEMPERATURE, BODY ACHES, FATIGUE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ELEVATED TEMPERATURE, BODY ACHES, FATIGUE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 20:03:58
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the ELEVATED TEMPERATURE, BODY ACHES, FATIGUE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ELEVATED TEMPERATURE, BODY ACHES, FATIGUE did not meet the AE reporting criteria.' answered with 'does not meet AE reporting Criteria.' (Site from DM).	John Villegas (b) (4)	13 Nov 2020 23:03:32

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the ELEVATED TEMPERATURE, BODY ACHES, FATIGUE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ELEVATED TEMPERATURE, BODY ACHES, FATIGUE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 20:49:07
User entered 'elevated temperature, body aches, fatigue'	(b) (4), (b) (6)	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	(b) (4), (b) (6)	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'four times daily (QID)'	(b) (4), (b) (6)	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '24 Sep 2020'	(b) (4), (b) (6)	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 03:53:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 03:53:07
Data point term sent to Coder	System	23 Nov 2020 19:25:17
User entered 'Apixaban'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'Blood Clots'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered '2 tabs bid for 7 days then 1 tab bid'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '4 Nov 2020'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 04:15:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 04:15:03
Data point term sent to Coder	System	23 Nov 2020 19:26:19
User entered 'Tramadol'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

[Indication](#)

Audit	User	Time (GMT)
User entered 'Left Calf Pain'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

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

Audit	User	Time (GMT)
User entered '4 Nov 2020'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:25:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 21:28:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:00
User entered 'USA-US017-2020-MRNA-1273-P301000003'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:02
User entered 'Yes (Y)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:03
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:05
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:07
User entered 'Yes (Y)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:09
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:10
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:12
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:16
User entered 'William'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:18
User entered 'Seger'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE-USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

Site Address: [Street](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	16 Nov 2020 17:57:10
DataPoint Un-verified.	System	16 Nov 2020 17:57:10
User entered '4505 Boat Club Road, Suite 400A'	System	16 Nov 2020 17:57:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 15:21:16
User closed query 'Please correct the street address. It has to be 4504 boat club road.	(b) (4), (b) (6)	13 Nov 2020 15:21:14
' (Site from CRA).		
Query 'Please correct the street address. It has to be 4504 boat club road.	(b) (4), (b) (6)	12 Nov 2020 18:56:26
' answered with 'CORRECTED' (Site from CRA).		
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 18:56:19
User opened query 'Please correct the street address. It has to be 4504 boat club road.	(b) (4), (b) (6)	12 Nov 2020 18:05:48
' (Site from CRA).		
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:21
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:19
User entered '4505 Boat Club Road, Suite 400A'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:50
User entered 'Fort Worth'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 15:21:22
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:56:19

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:52
User entered '76135'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:53
User entered 'US'	System	09 Nov 2020 18:02:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Nov 2020 17:57:10
User entered '1'	System	09 Nov 2020 18:02:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:00
User entered 'USA-US017-2020-MRNA-1273-P301000003'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:02
User entered 'Yes (Y)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:03
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:05
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:07
User entered 'Yes (Y)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:09
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:10
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:12
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:16
User entered 'William'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:18
User entered 'Seger'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE-USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

Site Address: [Street](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	16 Nov 2020 17:57:10
DataPoint Un-verified.	System	16 Nov 2020 17:57:10
User entered '4505 Boat Club Road, Suite 400A'	System	16 Nov 2020 17:57:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 15:21:16
User closed query 'Please correct the street address. It has to be 4504 boat club road.	(b) (4), (b) (6)	13 Nov 2020 15:21:14
' (Site from CRA).		
Query 'Please correct the street address. It has to be 4504 boat club road.	(b) (4), (b) (6)	12 Nov 2020 18:56:26
' answered with 'CORRECTED' (Site from CRA).		
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 18:56:19
User opened query 'Please correct the street address. It has to be 4504 boat club road.	(b) (4), (b) (6)	12 Nov 2020 18:05:48
' (Site from CRA).		
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:21
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:19
User entered '4505 Boat Club Road, Suite 400A'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:50
User entered 'Fort Worth'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 15:21:22
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:56:19

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:52
User entered '76135'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:53
User entered 'US'	System	09 Nov 2020 18:02:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Nov 2020 17:57:10
User entered '1'	System	09 Nov 2020 18:02:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:25:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '09/Nov/2020 18:02'	System	09 Nov 2020 18:02:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:25:48

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)	16 Nov 2020 17:56:46
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 18:02:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:00
User entered 'USA-US017-2020-MRNA-1273-P301000003'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Serious](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:02
User entered 'Yes (Y)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:03
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:05
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:07
User entered 'Yes (Y)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:09
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:10
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:12
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:16
User entered 'William'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:18
User entered 'Seger'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE-USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

Site Address: [Street](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	16 Nov 2020 17:57:10
DataPoint Un-verified.	System	16 Nov 2020 17:57:10
User entered '4505 Boat Club Road, Suite 400A'	System	16 Nov 2020 17:57:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 15:21:16
User closed query 'Please correct the street address. It has to be 4504 boat club road.	(b) (4), (b) (6)	13 Nov 2020 15:21:14
' (Site from CRA).		
Query 'Please correct the street address. It has to be 4504 boat club road.	(b) (4), (b) (6)	12 Nov 2020 18:56:26
' answered with 'CORRECTED' (Site from CRA).		
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 18:56:19
User opened query 'Please correct the street address. It has to be 4504 boat club road.	(b) (4), (b) (6)	12 Nov 2020 18:05:48
' (Site from CRA).		
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:21
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:19
User entered '4505 Boat Club Road, Suite 400A'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:50
User entered 'Fort Worth'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 15:21:22
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:56:19

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:52
User entered '76135'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:05:53
User entered 'US'	System	09 Nov 2020 18:02:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Nov 2020 17:57:10
User entered '1'	System	09 Nov 2020 18:02:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:25:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '16/Nov/2020 12:57'	System	16 Nov 2020 17:57:10

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:25:48

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 17:57:10