

US3492078 (Prod: UIC Project WISH CRS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:29:11

All time stamps listed in this document are displayed in GMT

US3492078

Form: Participant Creation

Generated On: 26 Nov 2020 09:29:11

[Participant ID](#)

US3492078

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

US3492078

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:11

Date of Birth (MMM yyyy)	(b) (6) 1927
Age	93
Age Units	YEARS
Age (Derived)	93
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 09:29:11

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:29:11

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:29:11

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:11

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:11

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

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:11

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

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:11

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

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:11

Condition	LEFT NEPHRECTOMY FOR KIDNEY CANCER
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 09:29:11

Condition	S/P RESECTION OF BASAL CELL CANCER
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:11

Condition	S/P CVA
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

US3492078

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:11

Condition	S/P CVA
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)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:11

Condition	S/P CVA WITH RESIDUAL RIGHT LOWER EXTREMITY WEAKNESS AND ATAXIA
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:11

Condition	DEPRESSION
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 (11)

Generated On: 26 Nov 2020 09:29:11

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:11

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 1932
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1932
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1932
Start Year (derived)	1932
Stop Month and Year (derived)	JAN 1932
Stop Year (derived)	1932

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:11

Condition	S/P CARDIAC ARREST WITH RESUSCITATION
Start date (dd MMM yyyy)	UN UNK 1973
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1973
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1973
Start Year (derived)	1973
Stop Month and Year (derived)	JAN 1973
Stop Year (derived)	1973

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:11

Condition	RIGHT LOWER EXTREMITY EDEMA
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:11

Condition	CORONARY ARTERY BYPASS GRAFT
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:11

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1932
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1932
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1932
Start Year (derived)	1932
Stop Month and Year (derived)	JAN 1932
Stop Year (derived)	1932

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Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:11

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	5 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:49 (24 HR)
Vital Signs Date and Time (derived)	5 SEP 2020 13:49
Height (<i>xxx.x</i>)	187.9 cm
Weight (<i>xxx.x</i>)	82.5 kg
BMI (<i>xxx.x</i>)	23.36686 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 09:29:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

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

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	5 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:11

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

What was the participant's randomization number? 190151

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 09:29:11

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 09:29:11

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	5 SEP 2020
Time of assessment (00:00-23:59)	14:49 (24 HR)
Vital Signs Date and Time (derived)	5 SEP 2020 14:49
Temperature (xxx.x)	35.6 C
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TYMPANIC
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	159 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: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	5 SEP 2020
Time of assessment (00:00-23:59)	16:15 (24 HR)
Vital Signs Date and Time (derived)	5 SEP 2020 16:15
Temperature (xxx.x)	35.6 C
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TYMPANIC
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	159 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 09:29:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	5 SEP 2020
What was the treatment time? (00:00-23:59)	15:59 (24 HR)
Treatment Date and Time (derived)	5 SEP 2020 15:59
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:11

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	5 SEP 2020
Collection time (<i>00:00-23:59</i>)	14:29 (24 HR)
Collection date and time (derived)	5 SEP 2020 14:29

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:29:11

Collection date (<i>dd MMM yyyy</i>)			5 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	14:15	5 SEP 2020 14:15
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

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 09:29:11

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**

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 05 SEP 2020 16:19

PC Close Date & Time 05 SEP 2020 18:49

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

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 05 SEP 2020 19:44

PC Close Date & Time 06 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:11

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**

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 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:11

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**

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 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE in °F**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:11

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 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:11

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**

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 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE in °F**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

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 ☐

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

05 SEP 2020 16:19

PC Close Date & Time

05 SEP 2020 18:49

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

05 SEP 2020 19:44

PC Close Date & Time

06 SEP 2020 11:59

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:11

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 ☐

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

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:11

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 ☐

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

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:11

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

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:11

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 ☐

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

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

05 SEP 2020 16:19

PC Close Date & Time

05 SEP 2020 18:49

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

05 SEP 2020 19:44

PC Close Date & Time

06 SEP 2020 11:59

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:11

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

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:11

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

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:11

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

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:11

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

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:11

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

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:11

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

US3492078

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492078

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492078

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

Was Contact Attempted?

Yes ☒

No ☐

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

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492078

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492078

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

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

US3492078

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492078

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

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

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	02 OCT 2020
Time of assessment (00:00-23:59)	13:24 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 13:24
Temperature (xxx.x)	97.3 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TYMPANIC
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	165 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	02 OCT 2020
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 14:55
Temperature (xxx.x)	36 C
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TYMPANIC
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3492078

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 OCT 2020

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

US3492078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

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)	02 OCT 2020
What was the treatment time? (00:00-23:59)	14:53 (24 HR)
Treatment Date and Time (derived)	02 OCT 2020 14:53
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

US3492078

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:11

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	02 OCT 2020
Collection time (<i>00:00-23:59</i>)	13:43 (24 HR)
Collection date and time (derived)	02 OCT 2020 13:43

US3492078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:29:11

Collection date (<i>dd MMM yyyy</i>)			02 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:50	02 OCT 2020 13:50
Nasopharyngeal Swab 2	No		

US3492078

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

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 96.8 °F

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

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

PC Time Stamp 02 OCT 2020 15:32

PC Open Date & Time 02 OCT 2020 15:13

PC Close Date & Time 02 OCT 2020 17:43

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

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 97.9 °F

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

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

PC Time Stamp	02 OCT 2020 18:39
PC Open Date & Time	02 OCT 2020 18:38
PC Close Date & Time	03 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 12:02

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp 04 OCT 2020 13:10

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:11

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 16:14

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 18:49

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:11

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

97.7 °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 07 OCT 2020 20:51

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 18:45

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

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

02 OCT 2020 15:32

PC Open Date & Time

02 OCT 2020 15:13

PC Close Date & Time

02 OCT 2020 17:43

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

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

02 OCT 2020 18:39

PC Open Date & Time

02 OCT 2020 18:38

PC Close Date & Time

03 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:11

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

03 OCT 2020 12:02

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:11

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

04 OCT 2020 13:10

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:11

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

4

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

05 OCT 2020 16:15

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:11

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

06 OCT 2020 18:49

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:11

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

07 OCT 2020 20:51

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:11

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

08 OCT 2020 18:45

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 15:33
PC Open Date & Time	02 OCT 2020 15:13
PC Close Date & Time	02 OCT 2020 17:43

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 18:40
PC Open Date & Time	02 OCT 2020 18:38
PC Close Date & Time	03 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:11

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 ☒

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:11

Yes ☐	
PC Time stamp	03 OCT 2020 12:03
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:11

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 ☒

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:11

Yes ☐	
PC Time stamp	04 OCT 2020 13:10
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:11

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 ☒

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:11

Yes ☐	
PC Time stamp	05 OCT 2020 16:15
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:11

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 ☒

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:11

Yes ☐	
PC Time stamp	06 OCT 2020 18:49
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:11

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 ☒

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:11

Yes ☐	
PC Time stamp	07 OCT 2020 20:51
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:11

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 ☒

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:11

Yes ☐	
PC Time stamp	08 OCT 2020 18:45
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3492078

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492078

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492078

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492078

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492078

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

Was Contact Attempted?

Yes ☒

No ☐

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

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492078

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492078

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	06 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3492078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	06 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	15:15 (24 HR)
Vital Signs Date and Time (derived)	06 NOV 2020 15:15
Temperature (<i>xxx.x</i>)	37.4 C
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TYMPANIC
Pulse (<i>xxx</i>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492078

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 NOV 2020

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

US3492078

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:11

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	06 NOV 2020
Collection time (<i>00:00-23:59</i>)	15:26 (24 HR)
Collection date and time (derived)	06 NOV 2020 15:26

US3492078

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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	08 NOV 2020 18:01:13
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2020 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2020 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

[Patient Cloud Close Date & Time](#)

20 NOV 2020 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2020 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2020 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

11 DEC 2020 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

18 DEC 2020 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

25 DEC 2020 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

01 JAN 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 JAN 2021 00:01
Patient Cloud Close Date & Time	08 JAN 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JAN 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JAN 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 JAN 2021 00:01

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29 JAN 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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05 FEB 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

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12 FEB 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

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15 FEB 2021 00:01

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19 FEB 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

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26 FEB 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

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

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US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

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19 MAR 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 APR 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 APR 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

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19 APR 2021 00:01

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23 APR 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 APR 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 AUG 2021 00:01

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20 AUG 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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°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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

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11 FEB 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

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18 FEB 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

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25 FEB 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

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28 FEB 2022 00:01

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04 MAR 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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°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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

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11 MAR 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

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14 MAR 2022 00:01

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18 MAR 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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°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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

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25 MAR 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

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01 APR 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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08 APR 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2022 00:01

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29 APR 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

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13 MAY 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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°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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

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03 JUN 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

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10 JUN 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

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24 JUN 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

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27 JUN 2022 00:01

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01 JUL 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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08 JUL 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

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15 JUL 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

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22 JUL 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2022 00:01

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29 JUL 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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05 AUG 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

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08 AUG 2022 00:01

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12 AUG 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2022 23:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2022 23:59

US3492078

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

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

US3492078

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3492078

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:29:11

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3492078

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:29:11

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

AEID	
Adverse event	SORENESS 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)	5 SEP 2020
Start time (00:00-23:59)	17:00 (24 HR)
AE start date and time (derived)	5 SEP 2020 17:00
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	7 SEP 2020
End time (00:00-23:59)	12:00 (24 HR)
AE End Date and Time (derived)	7 SEP 2020 12:00
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 (2)

Generated On: 26 Nov 2020 09:29:11

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	SOLICITED AE BUT COULD NOT GET EPRO TO WORK DESPITE CALLS TO MEDIDATA HELPDESK-CORRECTION-NOT SOLICITED SINCE NOT CAPTURED ON DIARY AND REPORTED VERBALLY TO SITE
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)	

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

AEID	USA-US101-2020-MRNA-1273-P30 1000006
Adverse event	HEMATOMA OF THE R 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)	03 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)	11 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)	11 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	17 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

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US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

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	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	

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

PARTICIPANT WAS WORKING
OUT ON TOTAL GYM MACHINE
AND INJURED RIGHT UPPER
LEG MUSCLE. ROM AND
STRENGTH WITHIN NORMAL
LIMITS AND BASELINE FOR
PARTICIPANT. SUBJECT
HOSPITALIZED 11NOV 2020
THROUGH 17NOV2020 FOR PAIN
AND SWELLING IN R LEG.
WORK UP INCLUDED RLE CT
WHICH SHOWED LARGE
INTRAMUSCULAR HEMATOMA
OF THE VASTUS LATERALUS
WITH MULTIPLE FOCI OF
ACTIVE EXTRAVASATION
FROM BRANCHES OF THE
PROFUNDA FEMORAL ARTERY.
NO DVT. APIXABAN HELD AND
ASA DISCONTINUED.
COLONOSCOPY PERFORMED
FOR SIGNS OF BLEEDING AND
COMPLAINT OF INTERMITTENT
DIARRHEA THAT HE DID NOT
REPORT AT D57 NOR ON
EDIARY OR SAFETY CALLS.
OVER COURSE OF ADMISSION
RECEIVED 3 UNITS PRBCS.
VASCULAR ANGIOGRAM AND
EMBOLIZATION PERFORMED
ON13NOV202., AT DISCHARGE
APIXABAN RESTARTED AT
2.5MG BID

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

US3492078

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:11

AEID	
Adverse event	
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)	
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	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
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	

US3492078

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:11

Congenital anomaly or birth defect		
Other medically important event		
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		
Concomitant Medication		
Concomitant Procedure		
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)		
Medically Attended AE Derived (CSA Programming Field Only)		
Admitted to ICU Derived (CSA Programming Field Only)		

US3492078

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:11

AEID	
Adverse event	
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)	
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	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
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	

US3492078

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:11

Congenital anomaly or birth defect		
Other medically important event		
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		
Concomitant Medication		
Concomitant Procedure		
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)		
Medically Attended AE Derived (CSA Programming Field Only)		
Admitted to ICU Derived (CSA Programming Field Only)		

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:29:11

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

Yes ☒

No ☐

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

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ☒
Indication	CORONARY ARTERY DISEASE
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 ☐

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

	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 2019
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	☒

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

Name of Medication	ELIQUIS
Prophylaxis	Yes ☐ No ☒
Indication	CEREBROVASCULAR DISEASE
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	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

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

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

Name of Medication	LASIX
Prophylaxis	Yes ☐ No ☒
Indication	CONGESTIVE HEART FAILURE
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 ☐

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

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

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

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

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

	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 2003
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	☒

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

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

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

	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	☒

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

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

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

	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	☒

US3492078

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:29:11

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3492078

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:29:11

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify

US3492078

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:29:11

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

US3492078

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:29:11

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 ☐

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

SAEID	USA-US101-2020-MRNA-1273-P301000006
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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:29:11

SAEID	USA-US101-2020-MRNA-1273-P301000006
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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	23/NOV/2020 20:08
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

US3492078 (Prod: UIC Project WISH CRS)

US3492078

Form: Participant Creation

Generated On: 26 Nov 2020 09:29:11

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3492078'	RWS_ENDPOINT ENDPOINT (b) (4) 	05 Sep 2020 18:40:42

US3492078

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:51:17

US3492078

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '05 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	05 Sep 2020 18:40:43

US3492078

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:51:17

US3492078

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	05 Sep 2020 19:51:17

US3492078

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered (b) (6) 1927'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	05 Sep 2020 18:40:44

US3492078

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:11

[Age](#)

Audit	User	Time (GMT)
User entered '93'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

US3492078

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:11

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	05 Sep 2020 19:52:36

US3492078

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '93'	System	05 Sep 2020 19:52:56

US3492078

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:11

Sex

Audit	User	Time (GMT)
User entered 'Male (M)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

US3492078

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:11

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

US3492078

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:11

White

Audit	User	Time (GMT)
User entered '1'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

US3492078

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:11

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

US3492078

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:11

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

US3492078

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

US3492078

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

US3492078

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:11

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

US3492078

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:11

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

US3492078

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:11

Unknown

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

US3492078

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:11

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

US3492078

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:56

US3492078

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	05 Sep 2020 19:52:56

US3492078

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '2020'	System	05 Sep 2020 19:52:56

US3492078

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:11

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:56

US3492078

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:56

US3492078

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:11

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:56

US3492078

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:56

US3492078

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:56

US3492078

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	05 Sep 2020 18:40:43

US3492078

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 19:53:14

US3492078

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:53:14

US3492078

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:29:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:53:42

US3492078

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 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)	13 Nov 2020 21:26:33
Data point term sent to Coder	System	13 Nov 2020 21:09:52
User closed query 'CDM-Coding: For coding purpose,Please split the term to two terms and record separately as; 1)CORONARY ARTERY DISEASE 2)CORONARY ARTERY BYPASS GRAFT' (Site from System).	System	13 Nov 2020 21:09:04
Query 'CDM-Coding: For coding purpose,Please split the term to two terms and record separately as; 1)CORONARY ARTERY DISEASE 2)CORONARY ARTERY BYPASS GRAFT' answered with 'done' (Site from System).	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:09:04
User entered 'CORONARY ARTERY DISEASE' reason for change: Data Entry Error	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:08:54
User opened query 'CDM-Coding: For coding purpose,Please split the term to two terms and record separately as; 1)CORONARY ARTERY DISEASE 2)CORONARY ARTERY BYPASS GRAFT' (Site from System).	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:46:46
Data point term sent to Coder	System	04 Nov 2020 20:15:50
Coding entries removed.	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:15:29
User entered 'CORONARY ARTERY DISEASE with coronary artery bypass graft' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:15:29
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:03:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:03:37
Data point term sent to Coder	System	05 Sep 2020 20:02:46
User entered 'Coronary artery disease'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:02:11

US3492078

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2003'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:02:11

US3492078

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:02:11

US3492078

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:02:11

US3492078

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:02:11

US3492078

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:02:11

US3492078

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	05 Sep 2020 20:02:11

US3492078

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '2003'	System	05 Sep 2020 20:02:11

US3492078

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 20:02:11

US3492078

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 20:02:11

US3492078

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4)	05 Sep 2020 20:04:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Sep 2020 20:04:37
Data point term sent to Coder	System	05 Sep 2020 20:03:49
User entered 'Atrial fibrillation'	Marla Schwarber (b) (4)	05 Sep 2020 20:03:13

US3492078

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:03:13

US3492078

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:03:13

US3492078

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:03:13

US3492078

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:03:13

US3492078

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:03:13

US3492078

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	05 Sep 2020 20:03:13

US3492078

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '2015'	System	05 Sep 2020 20:03:13

US3492078

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 20:03:13

US3492078

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 20:03:13

US3492078

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 20:05:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 20:05:37
Data point term sent to Coder	System	05 Sep 2020 20:04:49
User entered 'Congestive heart failure'	Marla Schwarber (b) (4)	05 Sep 2020 20:04:03

US3492078

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:04:03

US3492078

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:04:03

US3492078

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:04:03

US3492078

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:04:03

US3492078

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:04:03

US3492078

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	05 Sep 2020 20:04:03

US3492078

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '2015'	System	05 Sep 2020 20:04:03

US3492078

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 20:04:03

US3492078

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 20:04:03

US3492078

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:11

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Prostatic therapeutic procedures, PT: Prostatectomy, LLT: Prostatectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:10:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:10:55
Data point term sent to Coder	System	23 Nov 2020 15:09:56
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Prostatic therapeutic procedures, PT: Prostatectomy, LLT: Prostatectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:09:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:09:53
User closed query ' DM-Coding: please split this term into 2 separate entries. One record per line. 1)PROSTATE CANCER 2)PROSTATECTOMY [FOR PROSTATE CANCER]. Please update this term in accordance with your answer.' (Site from System).	System	23 Nov 2020 15:08:56
Query ' DM-Coding: please split this term into 2 separate entries. One record per line. 1)PROSTATE CANCER 2)PROSTATECTOMY [FOR PROSTATE CANCER]. Please update this term in accordance with your answer.' answered with 'will split into two separate entries' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 15:08:56
Data point term sent to Coder	System	23 Nov 2020 15:08:54
User entered 'PROSTATECTOMY' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 15:08:27
User opened query ' DM-Coding: please split this term into 2 separate entries. One record per line. 1)PROSTATE CANCER 2)PROSTATECTOMY [FOR PROSTATE CANCER]. Please update this term in accordance with your answer.' (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:26:51
Data point term sent to Coder	System	04 Nov 2020 20:16:51
Coding entries removed.	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:16:22
User entered 'prostatectomy for PROSTATE CANCER' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:16:22

US3492078

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 20:06:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 20:06:38
Data point term sent to Coder	System	05 Sep 2020 20:05:50
User entered 'Prostate cancer'	Marla Schwarber (b) (4)	05 Sep 2020 20:05:19

US3492078

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:05:19

US3492078

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:05:19

US3492078

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:05:19

US3492078

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:05:19

US3492078

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:05:19

US3492078

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	05 Sep 2020 20:05:19

US3492078

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '1998'	System	05 Sep 2020 20:05:19

US3492078

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	05 Sep 2020 20:05:19

US3492078

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '1998'	System	05 Sep 2020 20:05:19

US3492078

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:11

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Renal therapeutic procedures, PT: Nephrectomy, LLT: Nephrectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 14:09:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 14:09:46
Data point term sent to Coder	System	04 Nov 2020 20:17:54
Coding entries removed.	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:17:17
User entered 'left nephrectomy for KIDNEY CANCER' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:17:17
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Renal and urinary tract neoplasms malignant and unspecified, HLT: Renal neoplasms malignant, PT: Renal cancer, LLT: Kidney cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:07:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:07:38
Data point term sent to Coder	System	05 Sep 2020 20:06:51
User entered 'Kidney cancer'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:06:17

US3492078

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2013'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:06:17

US3492078

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:06:17

US3492078

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:06:17

US3492078

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2013'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:06:17

US3492078

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:06:17

US3492078

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	05 Sep 2020 20:06:17

US3492078

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '2013'	System	05 Sep 2020 20:06:17

US3492078

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	05 Sep 2020 20:06:17

US3492078

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '2013'	System	05 Sep 2020 20:06:17

US3492078

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Basal cell carcinoma excision - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:32:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:32:32
Data point term sent to Coder	System	04 Nov 2020 20:18:58
Coding entries removed.	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:18:39
User entered 's/p resection of BASAL CELL CANCER' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:18:39
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:08:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:08:38
Data point term sent to Coder	System	05 Sep 2020 20:07:54
User entered 'Basal cell cancer'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:07:17

US3492078

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:07:17

US3492078

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:07:17

US3492078

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:07:17

US3492078

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:07:17

US3492078

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:07:17

US3492078

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	05 Sep 2020 20:07:17

US3492078

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '2018'	System	05 Sep 2020 20:07:17

US3492078

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	05 Sep 2020 20:07:17

US3492078

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '2018'	System	05 Sep 2020 20:07:17

US3492078

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: CVA - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 06:02:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 06:02:50
Data point term sent to Coder	System	05 Sep 2020 20:08:55
User entered 'S/P CVA'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:08:53

US3492078

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:08:53

US3492078

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:08:53

US3492078

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	05 Sep 2020 20:17:39
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	05 Sep 2020 20:08:53
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:08:53

US3492078

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015' reason for change:	Marla Schwarber (b) (4)	05 Sep 2020 20:17:39
Data Entry Error	(b) (4)	
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:08:53
	(b) (4)	

US3492078

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:08:53

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	05 Sep 2020 20:08:53

US3492078

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '2015'	System	05 Sep 2020 20:08:53

US3492078

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	05 Sep 2020 20:17:39
User entered empty.	System	05 Sep 2020 20:08:53

US3492078

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '2015'	System	05 Sep 2020 20:17:39
User entered empty.	System	05 Sep 2020 20:08:53

US3492078

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: CVA - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 06:02:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 06:02:50
Data point term sent to Coder	System	05 Sep 2020 20:09:56
User entered 'S/P CVA'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:09:33

US3492078

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:09:33

US3492078

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:09:33

US3492078

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	05 Sep 2020 20:10:23
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	05 Sep 2020 20:09:33
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:09:33

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017' reason for change:	Marla Schwarber (b) (4)	05 Sep 2020 20:10:23
Data Entry Error	(b) (4)	
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:09:33
	(b) (4)	

US3492078

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:09:33

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	05 Sep 2020 20:09:33

US3492078

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '2017'	System	05 Sep 2020 20:09:33

US3492078

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	05 Sep 2020 20:10:23
User entered empty.	System	05 Sep 2020 20:09:33

US3492078

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '2017'	System	05 Sep 2020 20:10:23
User entered empty.	System	05 Sep 2020 20:09:33

US3492078

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: CVA - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 10:45:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 10:45:57
Data point term sent to Coder	System	05 Sep 2020 20:31:17
User entered 'S/P CVA with residual right lower extremity weakness and ataxia' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:31:11
Data point term sent to Coder	System	05 Sep 2020 20:11:58
User entered 'S/P CVA'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:11:41

US3492078

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:11:41

US3492078

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:11:41

US3492078

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	05 Sep 2020 20:35:07
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	05 Sep 2020 20:34:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 20:34:05
User entered 'No (N)'	Marla Schwarber (b) (4)	05 Sep 2020 20:11:41

US3492078

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 20:35:07
User entered 'UN UNK 2019'	Marla Schwarber (b) (4)	05 Sep 2020 20:11:41

US3492078

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:11:41

US3492078

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	05 Sep 2020 20:11:41

US3492078

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '2019'	System	05 Sep 2020 20:11:41

US3492078

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 20:35:07
User entered 'Jan 2019'	System	05 Sep 2020 20:11:41

US3492078

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 20:35:07
User entered '2019'	System	05 Sep 2020 20:11:41

US3492078

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:41:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:41:49
Data point term sent to Coder	System	08 Sep 2020 14:40:53
User entered 'Depression'	Marla Schwarber (b) (4)	08 Sep 2020 14:40:43

US3492078

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 14:40:43

US3492078

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 14:40:43

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 14:40:43

US3492078

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 14:40:43

US3492078

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 14:40:43

US3492078

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	08 Sep 2020 14:40:43

US3492078

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '2017'	System	08 Sep 2020 14:40:43

US3492078

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 14:40:43

US3492078

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 14:40:43

US3492078

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 21:28:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 21:28:39
Data point term sent to Coder	System	23 Oct 2020 21:27:25
User entered 'hyperlipidemia'	Michelle Agnoli (b) (4)	23 Oct 2020 21:26:50
	(b) (4)	

US3492078

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2003' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	09 Nov 2020 19:33:31
User entered 'un UNK 2005'	Michelle Agnoli (b) (4) (b) (4)	23 Oct 2020 21:26:50

US3492078

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Michelle Agnoli (b) (4) (b) (4)	23 Oct 2020 21:26:50

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Michelle Agnoli (b) (4) (b) (4)	23 Oct 2020 21:26:50

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	Michelle Agnoli (b) (4) (b) (4)	23 Oct 2020 21:26:50

US3492078

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Michelle Agnoli (b) (4) (b) (4)	23 Oct 2020 21:26:50

US3492078

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	09 Nov 2020 19:33:31
User entered 'Jan 2005'	System	23 Oct 2020 21:26:50

US3492078

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '2003'	System	09 Nov 2020 19:33:31
User entered '2005'	System	23 Oct 2020 21:26:50

US3492078

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 21:26:50

US3492078

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 21:26:50

US3492078

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 21:11:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 21:11:34
Data point term sent to Coder	System	13 Nov 2020 21:10:54
User closed query ' DM-Coding: please split this term into 2 separate entries. 1)TONSILLITIS 2)TONSILLECTOMY . One record per line. Please update this term in accordance with your answer.' (Site from System).	System	13 Nov 2020 21:10:50
Query ' DM-Coding: please split this term into 2 separate entries. 1)TONSILLITIS 2)TONSILLECTOMY . One record per line. Please update this term in accordance with your answer.' answered with 'done' (Site from System).	Michelle Agnoli (b) (4)	13 Nov 2020 21:10:50
User entered 'TONSILLITIS' reason for change: Data Entry Error	Michelle Agnoli (b) (4)	13 Nov 2020 21:10:41
User opened query ' DM-Coding: please split this term into 2 separate entries. 1)TONSILLITIS 2)TONSILLECTOMY . One record per line. Please update this term in accordance with your answer.' (Site from System).	Coder Import (b) (4)	12 Nov 2020 12:06:45
Data point term sent to Coder	System	04 Nov 2020 20:21:01
User entered 's/p tonsillectomy for tonsillitis'	Marla Schwarber (b) (4)	04 Nov 2020 20:20:57

US3492078

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'un UNK 1932'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:20:57

US3492078

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:20:57

US3492078

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:20:57

US3492078

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'un UNK 1932'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:20:57

US3492078

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:20:57

US3492078

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 1932'	System	04 Nov 2020 20:20:57

US3492078

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '1932'	System	04 Nov 2020 20:20:57

US3492078

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 1932'	System	04 Nov 2020 20:20:57

US3492078

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '1932'	System	04 Nov 2020 20:20:57

US3492078

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Cardiac arrest, LLT: Cardiac arrest - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 12:28:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 12:28:45
Data point term sent to Coder	System	04 Nov 2020 20:24:05
User entered 's/p cardiac arrest with resuscitation'	Marla Schwarber (b) (4)	04 Nov 2020 20:24:01

US3492078

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'un UNK 1973'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:24:01

US3492078

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:24:01

US3492078

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:24:01

US3492078

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'un UNK 1973'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:24:01

US3492078

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:24:01

US3492078

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 1973'	System	04 Nov 2020 20:24:01

US3492078

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '1973'	System	04 Nov 2020 20:24:01

US3492078

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 1973'	System	04 Nov 2020 20:24:01

US3492078

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '1973'	System	04 Nov 2020 20:24:01

US3492078

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:22:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:22:27
Data point term sent to Coder	System	06 Nov 2020 21:59:08
User entered 'Right lower extremity edema'	(b) (4), (b) (6) (b) (4)	06 Nov 2020 21:59:03

US3492078

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2003'	(b) (4), (b) (6)	06 Nov 2020 21:59:03

US3492078

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 21:59:03

US3492078

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 21:59:03

US3492078

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 21:59:03

US3492078

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 21:59:03

US3492078

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	06 Nov 2020 21:59:03

US3492078

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '2003'	System	06 Nov 2020 21:59:03

US3492078

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:59:03

US3492078

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:59:03

US3492078

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary artery bypass, LLT: Coronary artery bypass graft - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:10:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:10:46
Data point term sent to Coder	System	13 Nov 2020 21:09:53
User entered 'CORONARY ARTERY BYPASS GRAFT'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:09:41

US3492078

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'un UNK 2003'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:09:41

US3492078

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:09:41

US3492078

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:09:41

US3492078

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'un UNK 2003'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:09:41

US3492078

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:09:41

US3492078

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	13 Nov 2020 21:09:41

US3492078

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '2003'	System	13 Nov 2020 21:09:41

US3492078

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	13 Nov 2020 21:09:41

US3492078

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '2003'	System	13 Nov 2020 21:09:41

US3492078

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:12:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:12:34
Data point term sent to Coder	System	13 Nov 2020 21:11:59
User entered 'TONSILLECTOMY'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:11:30

US3492078

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'un UNK 1932'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:11:30

US3492078

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:11:30

US3492078

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	13 Nov 2020 21:12:11
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	13 Nov 2020 21:11:30
User entered 'No (N)'	Michelle Agnoli (b) (4)	13 Nov 2020 21:11:30

US3492078

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'un UNK 1932' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	13 Nov 2020 21:12:11
User entered empty.	Michelle Agnoli (b) (4)	13 Nov 2020 21:11:30

US3492078

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:11:30

US3492078

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 1932'	System	13 Nov 2020 21:11:30

US3492078

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '1932'	System	13 Nov 2020 21:11:30

US3492078

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 1932'	System	13 Nov 2020 21:12:11
User entered empty.	System	13 Nov 2020 21:11:30

US3492078

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '1932'	System	13 Nov 2020 21:12:11
User entered empty.	System	13 Nov 2020 21:11:30

US3492078

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:10:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:10:55
Data point term sent to Coder	System	23 Nov 2020 15:09:55
User entered 'PROSTATE CANCER'	(b) (4), (b) (6) (b) (4)	23 Nov 2020 15:09:43

US3492078

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	(b) (4), (b) (6)	23 Nov 2020 15:09:43

US3492078

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 15:09:43

US3492078

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 15:09:43

US3492078

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	(b) (4), (b) (6)	23 Nov 2020 15:09:43

US3492078

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 15:09:43

US3492078

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	23 Nov 2020 15:09:43

US3492078

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '1998'	System	23 Nov 2020 15:09:43

US3492078

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	23 Nov 2020 15:09:43

US3492078

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '1998'	System	23 Nov 2020 15:09:43

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:57:59

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:57:59

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '13:49'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:57:59

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '5 Sep 2020 13:49'	System	05 Sep 2020 19:57:59

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '187.9' cm	Marla Schwarber (b) (4)	05 Sep 2020 19:57:59
DataPoint set to visible.	(b) (4) System	05 Sep 2020 19:53:14

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '82.5' kg	Marla Schwarber (b) (4)	05 Sep 2020 19:57:59
DataPoint set to visible.	(b) (4) System	05 Sep 2020 19:53:14

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '23.36686'	System	05 Sep 2020 19:57:59
DataPoint set to visible.	System	05 Sep 2020 19:53:14

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	05 Sep 2020 19:57:59
DataPoint set to visible.	System	05 Sep 2020 19:53:14

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:28:43
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update accordingly.' answered with 'Corrected' (Site from DM).	Marla Schwarber (b) (4)	22 Sep 2020 00:58:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Sep 2020 00:58:00
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:34:58
User entered '36.8' C	Marla Schwarber (b) (4)	05 Sep 2020 19:57:59

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Marla Schwarber (b) (4)	22 Sep 2020 00:58:00
User entered 'Other (Other)'	Marla Schwarber (b) (4)	05 Sep 2020 19:57:59

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Marla Schwarber (b) (4)	22 Sep 2020 00:58:00
User entered 'Tympanic'	Marla Schwarber (b) (4)	05 Sep 2020 19:57:59

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4)	22 Sep 2020 00:58:00
User entered '58'	Marla Schwarber (b) (4)	05 Sep 2020 19:57:59

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Sep 2020 19:57:59

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4)	22 Sep 2020 00:58:00
User entered '20'	Marla Schwarber (b) (4)	05 Sep 2020 19:57:59

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Sep 2020 19:57:59

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4)	22 Sep 2020 00:58:17
User entered '148'	Marla Schwarber (b) (4)	05 Sep 2020 19:57:59

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 19:57:59

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4)	22 Sep 2020 00:58:17
User entered '74'	Marla Schwarber (b) (4)	05 Sep 2020 19:57:59

US3492078

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 19:57:59

US3492078

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:58:14

US3492078

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:58:14

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

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)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

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)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

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)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

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)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

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)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

[Other](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:00:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 20:00:03
User entered 'No (N)' reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 20:00:03
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 19:59:51
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

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'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

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'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '1'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:11

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:12:33

US3492078

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:12:33

US3492078

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:12:33

US3492078

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	05 Sep 2020 20:12:33

US3492078

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '05 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	05 Sep 2020 19:50:43

US3492078

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '190151'	RWS_ENDPOINT ENDPOINT (b) (4) 	05 Sep 2020 19:50:43

US3492078

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	05 Sep 2020 19:50:43

US3492078

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:11

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)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:13:25

US3492078

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:13:25

US3492078

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:13:25

US3492078

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:11

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:13:25

US3492078

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:11

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:13:25

US3492078

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:07:44
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:33:18

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:11

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:28:36
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' answered with 'Corrected' (Site from DM).	Marla Schwarber (b) (4)	22 Sep 2020 00:59:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Sep 2020 00:58:57
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:35:06
User entered '187.9' cm	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:11

[Weight](#)

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 00:59:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4)	22 Sep 2020 00:59:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 00:58:57
User entered 'kg' (non-conformant).	Marla Schwarber (b) (4)	22 Sep 2020 00:58:57
User entered '82.5' kg	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:11

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:28:36
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' answered with 'Corrected' (Site from DM).	Marla Schwarber (b) (4)	22 Sep 2020 00:59:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Sep 2020 00:58:57
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:35:06
User entered '187.9' cm	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:11

Weight

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 00:59:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4)	22 Sep 2020 00:59:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 00:58:57
User entered 'kg' (non-conformant).	Marla Schwarber (b) (4)	22 Sep 2020 00:58:57
User entered '82.5' kg	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17
	(b) (4)	

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '14:49'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '5 Sep 2020 14:49'	System	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 14:47:03
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 'NCS' (Site from System).	Marla Schwarber (b) (4)	17 Sep 2020 17:34:40
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 00:29:32
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:24:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Sep 2020 21:24:29
User entered '35.6' C reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 21:24:29
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:14:17
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)' reason for change: Data Marla Schwarber Entry Error	(b) (4)	05 Sep 2020 21:24:29
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Tympanic' reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 21:24:29
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:24:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Sep 2020 21:24:29
User entered '56' reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 21:24:29
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:14:17
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Sep 2020 21:24:29
User entered empty.	System	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:24:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Sep 2020 21:24:29
User entered '20' reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 21:24:29
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:14:17
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Sep 2020 21:24:29
User entered empty.	System	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 15:12:06
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Marla Schwarber (b) (4)	05 Sep 2020 21:24:40
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	05 Sep 2020 21:24:29
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:24:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Sep 2020 21:24:29
User entered '159' reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 21:24:29
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:14:17
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 21:24:29
User entered empty.	System	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:24:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Sep 2020 21:24:29
User entered '80' reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 21:24:29
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:14:17
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 21:24:29
User entered empty.	System	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:11

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:28:36
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' answered with 'Corrected' (Site from DM).	Marla Schwarber (b) (4)	22 Sep 2020 00:59:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Sep 2020 00:58:57
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:35:06
User entered '187.9' cm	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:11

Weight

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 00:59:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4)	22 Sep 2020 00:59:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 00:58:57
User entered 'kg' (non-conformant).	Marla Schwarber (b) (4)	22 Sep 2020 00:58:57
User entered '82.5' kg	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 21:23:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 21:23:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 21:23:18
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:14:17
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Sep 2020' reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 21:23:18
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '16:15' reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 21:23:18
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '5 Sep 2020 16:15'	System	05 Sep 2020 21:23:18
User entered empty.	System	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 14:47:08
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 'NCS' (Site from System).	Marla Schwarber (b) (4)	17 Sep 2020 17:35:02
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 00:29:32
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:29:34
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Sep 2020 21:29:34
User entered '35.6' C reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 21:29:34
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:23:18
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)' reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 21:29:34
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Tympanic' reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 21:29:34
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:29:34
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Sep 2020 21:29:34
User entered '56' reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 21:29:34
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:23:18
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Sep 2020 21:29:34
User entered empty.	System	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:29:34
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Sep 2020 21:29:34
User entered '20' reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 21:29:34
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:23:18
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Sep 2020 21:29:34
User entered empty.	System	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 15:12:13
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Marla Schwarber (b) (4)	05 Sep 2020 21:29:48
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	05 Sep 2020 21:29:34
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:29:34
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Sep 2020 21:29:34
User entered '159' reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 21:29:34
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:23:18
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 21:29:34
User entered empty.	System	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:29:34
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Sep 2020 21:29:34
User entered '80' reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 21:29:34
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:23:18
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:14:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 21:29:34
User entered empty.	System	05 Sep 2020 20:14:17

US3492078

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:11

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:36

US3492078

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:36

US3492078

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 15:10:36

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 15:10:36

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 15:10:36

US3492078

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 15:10:36

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 15:10:36

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '15:59'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 15:10:36

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '5 Sep 2020 15:59'	System	08 Sep 2020 15:10:36

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 15:10:36

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	08 Sep 2020 15:10:36

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 15:10:36

US3492078

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:18:26

US3492078

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:18:26

US3492078

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:29'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:18:26

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '5 Sep 2020 14:29'	System	05 Sep 2020 20:18:26

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:18:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:11

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Marla Schwarber (b) (4)	05 Sep 2020 20:18:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:18:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '14:15'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:18:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '5 Sep 2020 14:15'	System	05 Sep 2020 20:18:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:11

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Marla Schwarber (b) (4)	05 Sep 2020 20:18:59

US3492078

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:19:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 20:19:13
User entered 'No (N)' reason for change: Data Entry Error	Marla Schwarber (b) (4)	05 Sep 2020 20:19:13
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:18:59
User entered empty.	Marla Schwarber (b) (4)	05 Sep 2020 20:18:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:18:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 20:18:59

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 14:37:36

US3492078

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 14:37:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 16:19'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 18:49'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:10:36

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 19:44'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 2'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 3'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 4'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 5'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 6'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 7'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 16:19'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 18:49'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 19:44'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 2'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 3'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 4'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 5'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 6'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 7'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 16:19'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 18:49'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 19:44'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 2'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 3'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 4'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 5'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 6'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 7'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	14 Sep 2020 19:50:26

US3492078

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Elena Llinas (b) (4) (b) (4)	14 Sep 2020 19:50:26

US3492078

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elena Llinas (b) (4) (b) (4)	14 Sep 2020 19:50:26

US3492078

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elena Llinas (b) (4) (b) (4)	14 Sep 2020 19:50:26

US3492078

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	14 Sep 2020 19:50:30

US3492078

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 19:50:30

US3492078

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	21 Sep 2020 21:00:34

US3492078

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Elena Llinas (b) (4) (b) (4)	21 Sep 2020 21:00:34

US3492078

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elena Llinas (b) (4) (b) (4)	21 Sep 2020 21:00:34

US3492078

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elena Llinas (b) (4) (b) (4)	21 Sep 2020 21:00:34

US3492078

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	21 Sep 2020 21:00:41

US3492078

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 21:00:41

US3492078

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	29 Sep 2020 21:26:06

US3492078

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Elena Llinas (b) (4) (b) (4)	29 Sep 2020 21:26:06

US3492078

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elena Llinas (b) (4) (b) (4)	29 Sep 2020 21:26:06

US3492078

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elena Llinas (b) (4) (b) (4)	29 Sep 2020 21:26:06

US3492078

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	29 Sep 2020 21:26:09

US3492078

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 21:26:09

US3492078

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:07:11

US3492078

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:07:11

US3492078

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:07:11

US3492078

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	02 Oct 2020 19:07:11

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '13:24'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '02 Oct 2020 13:24'	System	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.3' F	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'tympanic'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '16'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '165'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '78'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 20:24:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 20:24:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Michelle Agnoli (b) (4)	02 Oct 2020 20:24:07
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 19:08:13
User entered empty.	Diana Bahena (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020' reason for change: Data Entry Error	Michelle Agnoli (b) (4)	02 Oct 2020 20:24:07
User entered empty.	Diana Bahena (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '14:55' reason for change: Data Entry Error	Michelle Agnoli (b) (4)	02 Oct 2020 20:24:07
User entered empty.	Diana Bahena (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '02 Oct 2020 14:55'	System	02 Oct 2020 20:24:07
User entered empty.	System	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36' C reason for change: Data Entry Error	Michelle Agnoli (b) (4)	02 Oct 2020 20:24:07
User entered empty.	Diana Bahena (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)' reason for change: Data Entry Error	Michelle Agnoli (b) (4)	02 Oct 2020 20:24:07
User entered empty.	Diana Bahena (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'tympanic' reason for change: Data Entry Error	Michelle Agnoli (b) (4)	02 Oct 2020 20:24:07
User entered empty.	Diana Bahena (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '62' reason for change: Data Entry Error	Michelle Agnoli (b) (4)	02 Oct 2020 20:24:07
User entered empty.	Diana Bahena (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Oct 2020 20:24:07
User entered empty.	System	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '16' reason for change: Data Entry Error	Michelle Agnoli (b) (4)	02 Oct 2020 20:24:07
User entered empty.	Diana Bahena (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Oct 2020 20:24:07
User entered empty.	System	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '134' reason for change: Data Entry Error	Michelle Agnoli (b) (4)	02 Oct 2020 20:24:07
User entered empty.	Diana Bahena (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 20:24:07
User entered empty.	System	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '71' reason for change: Data Entry Error	Michelle Agnoli (b) (4)	02 Oct 2020 20:24:07
User entered empty.	Diana Bahena (b) (4)	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 20:24:07
User entered empty.	System	02 Oct 2020 19:08:13

US3492078

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:36

US3492078

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:36

US3492078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:25:24

US3492078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:25:24

US3492078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	Michelle Agnoli (b) (4)	02 Oct 2020 20:25:24

US3492078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 20:25:24

US3492078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:25:24

US3492078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '14:53'	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:25:24

US3492078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '02 Oct 2020 14:53'	System	02 Oct 2020 20:25:24

US3492078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:25:24

US3492078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	02 Oct 2020 20:25:24

US3492078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 20:25:24

US3492078

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:54

US3492078

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:54

US3492078

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:43'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:54

US3492078

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '02 Oct 2020 13:43'	System	02 Oct 2020 19:08:54

US3492078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:29:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:09:15

US3492078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:11

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Diana Bahena (b) (4)	02 Oct 2020 19:09:15

US3492078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:09:15

US3492078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '13:50'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:09:15

US3492078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '02 Oct 2020 13:50'	System	02 Oct 2020 19:09:15

US3492078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:11

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Diana Bahena (b) (4)	02 Oct 2020 19:09:15

US3492078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:09:15

US3492078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:09:15

US3492078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:09:15

US3492078

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:09:20

US3492078

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:09:20

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:30:13', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd76295b1-8028-4e9d-8a04-61eb531bc504'	System	03 Oct 2020 17:02:37
User entered 'Yes (Y)'	System	03 Oct 2020 17:02:37

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:30:46', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd76295b1-8028-4e9d-8a04-61eb531bc504'	System	03 Oct 2020 17:02:37
User entered '96.8'	System	03 Oct 2020 17:02:37

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:31:59', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd76295b1-8028-4e9d-8a04-61eb531bc504'	System	03 Oct 2020 17:02:37
User entered 'No (N)'	System	03 Oct 2020 17:02:37

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:32:08', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd76295b1-8028-4e9d-8a04-61eb531bc504'	System	03 Oct 2020 17:02:37
User entered '02 Oct 2020 15:32'	System	03 Oct 2020 17:02:37

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 15:13'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 17:43'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:26', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '472f2ec1-4555-493c-9fea-7c3312c723bd' User entered 'Yes (Y)'	System	03 Oct 2020 17:02:42

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:30', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '472f2ec1-4555-493c-9fea-7c3312c723bd' User entered '97.9'	System	03 Oct 2020 17:02:42

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:32', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '472f2ec1-4555-493c-9fea-7c3312c723bd' User entered 'No (N)'	System	03 Oct 2020 17:02:42

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:35', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '472f2ec1-4555-493c-9fea-7c3312c723bd' User entered '02 Oct 2020 18:39'	System	03 Oct 2020 17:02:42
	System	03 Oct 2020 17:02:42

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 18:38'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 2'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:30', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '76d695f3-9084-4708-bd44-ee5bcfb32d93'	System	03 Oct 2020 17:02:44
User entered 'Yes (Y)'	System	03 Oct 2020 17:02:44

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:34', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '76d695f3-9084-4708-bd44-ee5bcfb32d93'	System	03 Oct 2020 17:02:44
User entered '98.1'	System	03 Oct 2020 17:02:44

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:37', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '76d695f3-9084-4708-bd44-ee5bcfb32d93'	System	03 Oct 2020 17:02:44
User entered 'No (N)'	System	03 Oct 2020 17:02:44

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:39', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '76d695f3-9084-4708-bd44-ee5bcfb32d93' User entered '03 Oct 2020 12:02'	System	03 Oct 2020 17:02:44
	System	03 Oct 2020 17:02:44

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 3'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:26', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'a2802828-760f-41f3-a7f3-8738056948ee'	System	04 Oct 2020 18:10:41
User entered 'Yes (Y)'	System	04 Oct 2020 18:10:41

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:33', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'a2802828-760f-41f3-a7f3-8738056948ee' User entered '98.0'	System	04 Oct 2020 18:10:41

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:35', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'a2802828-760f-41f3-a7f3-8738056948ee'	System	04 Oct 2020 18:10:41
User entered 'No (N)'	System	04 Oct 2020 18:10:41

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:37', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'a2802828-760f-41f3-a7f3-8738056948ee'	System	04 Oct 2020 18:10:41
User entered '04 Oct 2020 13:10'	System	04 Oct 2020 18:10:41

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 4'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:14:05', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd2c33fc1-cbda-4896-9d47-5c5680d0c1ac'	System	05 Oct 2020 21:14:18
User entered 'Yes (Y)'	System	05 Oct 2020 21:14:18

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:14:11', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd2c33fc1-cbda-4896-9d47-5c5680d0c1ac'	System	05 Oct 2020 21:14:18
User entered '97.9'	System	05 Oct 2020 21:14:18

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:14:13', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd2c33fc1-cbda-4896-9d47-5c5680d0c1ac'	System	05 Oct 2020 21:14:18
User entered 'No (N)'	System	05 Oct 2020 21:14:18

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:14:16', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd2c33fc1-cbda-4896-9d47-5c5680d0c1ac' User entered '05 Oct 2020 16:14'	System	05 Oct 2020 21:14:18
	System	05 Oct 2020 21:14:18

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 5'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:14', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f8a2c1a7-2d91-460c-a660-030100127d70'	System	06 Oct 2020 23:49:26
User entered 'Yes (Y)'	System	06 Oct 2020 23:49:26

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:20', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f8a2c1a7-2d91-460c-a660-030100127d70'	System	06 Oct 2020 23:49:26
User entered '98.0'	System	06 Oct 2020 23:49:26

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:22', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f8a2c1a7-2d91-460c-a660-030100127d70'	System	06 Oct 2020 23:49:26
User entered 'No (N)'	System	06 Oct 2020 23:49:26

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:24', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f8a2c1a7-2d91-460c-a660-030100127d70'	System	06 Oct 2020 23:49:26
User entered '06 Oct 2020 18:49'	System	06 Oct 2020 23:49:26

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 6'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:50:57', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '791036a3-a496-4de2-9cc8-553b0123b062'	System	08 Oct 2020 01:51:08
User entered 'Yes (Y)'	System	08 Oct 2020 01:51:08

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:03', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '791036a3-a496-4de2-9cc8-553b0123b062'	System	08 Oct 2020 01:51:08
User entered '97.7'	System	08 Oct 2020 01:51:08

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:04', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '791036a3-a496-4de2-9cc8-553b0123b062'	System	08 Oct 2020 01:51:08
User entered 'No (N)'	System	08 Oct 2020 01:51:08

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:06', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '791036a3-a496-4de2-9cc8-553b0123b062'	System	08 Oct 2020 01:51:08
User entered '07 Oct 2020 20:51'	System	08 Oct 2020 01:51:08

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 7'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:09', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '19e3f236-bada-4065-b6f0-b25b1fff164d' User entered 'Yes (Y)'	System	08 Oct 2020 23:45:20
	System	08 Oct 2020 23:45:20

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:14', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '19e3f236-bada-4065-b6f0-b25b1fff164d' User entered '98.1'	System	08 Oct 2020 23:45:20

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:15', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '19e3f236-bada-4065-b6f0-b25b1fff164d'	System	08 Oct 2020 23:45:20
User entered 'No (N)'	System	08 Oct 2020 23:45:20

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:17', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '19e3f236-bada-4065-b6f0-b25b1fff164d'	System	08 Oct 2020 23:45:20
User entered '08 Oct 2020 18:45'	System	08 Oct 2020 23:45:20

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:32:15', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0ab86b09-b137-41b4-b8f6-9ec500bf1511'	System	03 Oct 2020 17:02:38
User entered 'None (1)'	System	03 Oct 2020 17:02:38

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:32:18', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0ab86b09-b137-41b4-b8f6-9ec500bf1511'	System	03 Oct 2020 17:02:38
User entered 'No (N)'	System	03 Oct 2020 17:02:38

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:32:23', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0ab86b09-b137-41b4-b8f6-9ec500bf1511'	System	03 Oct 2020 17:02:38
User entered 'No (N)'	System	03 Oct 2020 17:02:38

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:32:29', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0ab86b09-b137-41b4-b8f6-9ec500bf1511'	System	03 Oct 2020 17:02:38
User entered 'None (1)'	System	03 Oct 2020 17:02:38

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:32:33', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0ab86b09-b137-41b4-b8f6-9ec500bf1511'	System	03 Oct 2020 17:02:38
User entered '02 Oct 2020 15:32'	System	03 Oct 2020 17:02:38

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 15:13'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 17:43'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:41', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f911910e-34c5-4d19-ba5f-109e77631f1e'	System	03 Oct 2020 17:02:42
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 17:02:42

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:43', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f911910e-34c5-4d19-ba5f-109e77631f1e'	System	03 Oct 2020 17:02:42
User entered 'No (N)'	System	03 Oct 2020 17:02:42

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:44', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f911910e-34c5-4d19-ba5f-109e77631f1e'	System	03 Oct 2020 17:02:42
User entered 'No (N)'	System	03 Oct 2020 17:02:42

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:46', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f911910e-34c5-4d19-ba5f-109e77631f1e'	System	03 Oct 2020 17:02:42
User entered 'None (1)'	System	03 Oct 2020 17:02:42

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:47', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f911910e-34c5-4d19-ba5f-109e77631f1e'	System	03 Oct 2020 17:02:42
User entered '02 Oct 2020 18:39'	System	03 Oct 2020 17:02:42

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 18:38'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 2'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:42', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '27a3318e-7360-4f57-95d4-20cba2f752e8'	System	03 Oct 2020 17:02:52
User entered 'None (1)'	System	03 Oct 2020 17:02:52

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:44', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '27a3318e-7360-4f57-95d4-20cba2f752e8'	System	03 Oct 2020 17:02:52
User entered 'No (N)'	System	03 Oct 2020 17:02:52

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:46', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '27a3318e-7360-4f57-95d4-20cba2f752e8'	System	03 Oct 2020 17:02:52
User entered 'No (N)'	System	03 Oct 2020 17:02:52

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:47', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '27a3318e-7360-4f57-95d4-20cba2f752e8'	System	03 Oct 2020 17:02:52
User entered 'None (1)'	System	03 Oct 2020 17:02:52

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:49', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '27a3318e-7360-4f57-95d4-20cba2f752e8' User entered '03 Oct 2020 12:02'	System	03 Oct 2020 17:02:52
	System	03 Oct 2020 17:02:52

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 3'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:40', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '516491b9-1140-46b8-bbde-619922d37ff7'	System	04 Oct 2020 18:10:49
User entered 'None (1)'	System	04 Oct 2020 18:10:49

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:42', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '516491b9-1140-46b8-bbde-619922d37ff7'	System	04 Oct 2020 18:10:49
User entered 'No (N)'	System	04 Oct 2020 18:10:49

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:43', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '516491b9-1140-46b8-bbde-619922d37ff7'	System	04 Oct 2020 18:10:49
User entered 'No (N)'	System	04 Oct 2020 18:10:49

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:45', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '516491b9-1140-46b8-bbde-619922d37ff7'	System	04 Oct 2020 18:10:49
User entered 'None (1)'	System	04 Oct 2020 18:10:49

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:46', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '516491b9-1140-46b8-bbde-619922d37ff7'	System	04 Oct 2020 18:10:49
User entered '04 Oct 2020 13:10'	System	04 Oct 2020 18:10:49

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 4'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:14:20', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2a915d3a-779b-4c23-812d-795445a8174d'	System	05 Oct 2020 21:15:03
User entered 'None (1)'	System	05 Oct 2020 21:15:03

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:14:21', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2a915d3a-779b-4c23-812d-795445a8174d'	System	05 Oct 2020 21:15:03
User entered 'No (N)'	System	05 Oct 2020 21:15:03

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:14:24', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2a915d3a-779b-4c23-812d-795445a8174d'	System	05 Oct 2020 21:15:03
User entered 'Yes (Y)'	System	05 Oct 2020 21:15:03

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:11

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:14:48', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2a915d3a-779b-4c23-812d-795445a8174d' User entered '4'	System	05 Oct 2020 21:15:03

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:14:51', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2a915d3a-779b-4c23-812d-795445a8174d'	System	05 Oct 2020 21:15:03
User entered 'None (1)'	System	05 Oct 2020 21:15:03

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:15:01', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2a915d3a-779b-4c23-812d-795445a8174d' User entered '05 Oct 2020 16:15'	System	05 Oct 2020 21:15:03
	System	05 Oct 2020 21:15:03

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 5'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:28', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '61f2dec3-28fd-4d4b-9620-adc37cf02f50'	System	06 Oct 2020 23:49:42
User entered 'None (1)'	System	06 Oct 2020 23:49:42

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:30', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '61f2dec3-28fd-4d4b-9620-adc37cf02f50'	System	06 Oct 2020 23:49:42
User entered 'No (N)'	System	06 Oct 2020 23:49:42

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:32', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '61f2dec3-28fd-4d4b-9620-adc37cf02f50'	System	06 Oct 2020 23:49:42
User entered 'No (N)'	System	06 Oct 2020 23:49:42

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:34', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '61f2dec3-28fd-4d4b-9620-adc37cf02f50'	System	06 Oct 2020 23:49:42
User entered 'None (1)'	System	06 Oct 2020 23:49:42

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:36', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '61f2dec3-28fd-4d4b-9620-adc37cf02f50'	System	06 Oct 2020 23:49:42
User entered '06 Oct 2020 18:49'	System	06 Oct 2020 23:49:42

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 6'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:09', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '25e75d1a-a291-4313-af8b-261615d104e9' User entered 'None (1)'	System	08 Oct 2020 01:51:19
	System	08 Oct 2020 01:51:19

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:11', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '25e75d1a-a291-4313-af8b-261615d104e9' User entered 'No (N)'	System	08 Oct 2020 01:51:19
	System	08 Oct 2020 01:51:19

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:12', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '25e75d1a-a291-4313-af8b-261615d104e9'	System	08 Oct 2020 01:51:19
User entered 'No (N)'	System	08 Oct 2020 01:51:19

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:14', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '25e75d1a-a291-4313-af8b-261615d104e9' User entered 'None (1)'	System	08 Oct 2020 01:51:19
	System	08 Oct 2020 01:51:19

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:16', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '25e75d1a-a291-4313-af8b-261615d104e9' User entered '07 Oct 2020 20:51'	System	08 Oct 2020 01:51:19

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 7'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:20', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd2b640a4-3fe1-4c99-a030-9e816aae0966'	System	08 Oct 2020 23:45:30
User entered 'None (1)'	System	08 Oct 2020 23:45:30

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:22', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd2b640a4-3fe1-4c99-a030-9e816aae0966'	System	08 Oct 2020 23:45:30
User entered 'No (N)'	System	08 Oct 2020 23:45:30

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:24', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd2b640a4-3fe1-4c99-a030-9e816aae0966'	System	08 Oct 2020 23:45:30
User entered 'No (N)'	System	08 Oct 2020 23:45:30

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:25', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd2b640a4-3fe1-4c99-a030-9e816aae0966'	System	08 Oct 2020 23:45:30
User entered 'None (1)'	System	08 Oct 2020 23:45:30

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:27', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd2b640a4-3fe1-4c99-a030-9e816aae0966'	System	08 Oct 2020 23:45:30
User entered '08 Oct 2020 18:45'	System	08 Oct 2020 23:45:30

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:33:04', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0bf80edb-230d-4f1a-8465-1eeaa99f933a'	System	03 Oct 2020 17:02:40
User entered 'None (0)'	System	03 Oct 2020 17:02:40

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:33:14', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0bf80edb-230d-4f1a-8465-1eeaa99f933a'	System	03 Oct 2020 17:02:40
User entered 'None (0)'	System	03 Oct 2020 17:02:40

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:33:22', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0bf80edb-230d-4f1a-8465-1eeaa99f933a' User entered 'None (0)'	System	03 Oct 2020 17:02:40
	System	03 Oct 2020 17:02:40

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:33:29', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0bf80edb-230d-4f1a-8465-1eeaa99f933a' User entered 'None (0)'	System	03 Oct 2020 17:02:40

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:33:34', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0bf80edb-230d-4f1a-8465-1eeaa99f933a' User entered 'None (0)'	System	03 Oct 2020 17:02:40
	System	03 Oct 2020 17:02:40

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:33:43', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0bf80edb-230d-4f1a-8465-1eeaa99f933a' User entered 'None (0)'	System	03 Oct 2020 17:02:40
	System	03 Oct 2020 17:02:40

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:33:51', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0bf80edb-230d-4f1a-8465-1eeaa99f933a'	System	03 Oct 2020 17:02:40
User entered 'No (N)'	System	03 Oct 2020 17:02:40

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:33:53', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0bf80edb-230d-4f1a-8465-1eeaa99f933a' User entered '02 Oct 2020 15:33'	System	03 Oct 2020 17:02:40
	System	03 Oct 2020 17:02:40

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 15:13'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 17:43'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:51', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8dbfac0e-d694-4a6e-9ac4-24c4168b3617'	System	03 Oct 2020 17:02:44
User entered 'None (0)'	System	03 Oct 2020 17:02:44

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:52', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8dbfac0e-d694-4a6e-9ac4-24c4168b3617'	System	03 Oct 2020 17:02:44
User entered 'None (0)'	System	03 Oct 2020 17:02:44

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:53', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8dbfac0e-d694-4a6e-9ac4-24c4168b3617'	System	03 Oct 2020 17:02:44
User entered 'None (0)'	System	03 Oct 2020 17:02:44

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:55', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8dbfac0e-d694-4a6e-9ac4-24c4168b3617'	System	03 Oct 2020 17:02:44
User entered 'None (0)'	System	03 Oct 2020 17:02:44

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:56', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8dbfac0e-d694-4a6e-9ac4-24c4168b3617'	System	03 Oct 2020 17:02:44
User entered 'None (0)'	System	03 Oct 2020 17:02:44

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:58', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8dbfac0e-d694-4a6e-9ac4-24c4168b3617'	System	03 Oct 2020 17:02:44
User entered 'None (0)'	System	03 Oct 2020 17:02:44

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:40:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8dbfac0e-d694-4a6e-9ac4-24c4168b3617'	System	03 Oct 2020 17:02:44
User entered 'No (N)'	System	03 Oct 2020 17:02:44

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:40:02', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8dbfac0e-d694-4a6e-9ac4-24c4168b3617'	System	03 Oct 2020 17:02:44
User entered '02 Oct 2020 18:40'	System	03 Oct 2020 17:02:44

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 18:38'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 2'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:52', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f68dba7c-56ed-4694-99ee-6da81d72d8eb' User entered 'None (0)'	System	03 Oct 2020 17:03:07
	System	03 Oct 2020 17:03:07

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:54', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f68dba7c-56ed-4694-99ee-6da81d72d8eb' User entered 'None (0)'	System	03 Oct 2020 17:03:07
	System	03 Oct 2020 17:03:07

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:55', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f68dba7c-56ed-4694-99ee-6da81d72d8eb' User entered 'None (0)'	System	03 Oct 2020 17:03:07
	System	03 Oct 2020 17:03:07

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:57', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f68dba7c-56ed-4694-99ee-6da81d72d8eb' User entered 'None (0)'	System	03 Oct 2020 17:03:07
	System	03 Oct 2020 17:03:07

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:59', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f68dba7c-56ed-4694-99ee-6da81d72d8eb' User entered 'None (0)'	System	03 Oct 2020 17:03:07
	System	03 Oct 2020 17:03:07

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:03:01', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f68dba7c-56ed-4694-99ee-6da81d72d8eb' User entered 'None (0)'	System	03 Oct 2020 17:03:07
	System	03 Oct 2020 17:03:07

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:03:03', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f68dba7c-56ed-4694-99ee-6da81d72d8eb' User entered 'No (N)'	System	03 Oct 2020 17:03:07

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:03:05', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f68dba7c-56ed-4694-99ee-6da81d72d8eb' User entered '03 Oct 2020 12:03'	System	03 Oct 2020 17:03:07
	System	03 Oct 2020 17:03:07

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 3'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:49', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '77c7d4b1-beb3-4320-97d4-a1b0b73f65b3'	System	04 Oct 2020 18:11:01
User entered 'None (0)'	System	04 Oct 2020 18:11:01

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:51', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '77c7d4b1-beb3-4320-97d4-a1b0b73f65b3'	System	04 Oct 2020 18:11:01
User entered 'None (0)'	System	04 Oct 2020 18:11:01

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:52', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '77c7d4b1-beb3-4320-97d4-a1b0b73f65b3'	System	04 Oct 2020 18:11:01
User entered 'None (0)'	System	04 Oct 2020 18:11:01

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:53', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '77c7d4b1-beb3-4320-97d4-a1b0b73f65b3'	System	04 Oct 2020 18:11:01
User entered 'None (0)'	System	04 Oct 2020 18:11:01

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:54', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '77c7d4b1-beb3-4320-97d4-a1b0b73f65b3'	System	04 Oct 2020 18:11:01
User entered 'None (0)'	System	04 Oct 2020 18:11:01

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:55', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '77c7d4b1-beb3-4320-97d4-a1b0b73f65b3'	System	04 Oct 2020 18:11:01
User entered 'None (0)'	System	04 Oct 2020 18:11:01

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:56', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '77c7d4b1-beb3-4320-97d4-a1b0b73f65b3'	System	04 Oct 2020 18:11:01
User entered 'No (N)'	System	04 Oct 2020 18:11:01

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:58', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '77c7d4b1-beb3-4320-97d4-a1b0b73f65b3'	System	04 Oct 2020 18:11:01
User entered '04 Oct 2020 13:10'	System	04 Oct 2020 18:11:01

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 4'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:15:04', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f976334-6802-40ba-a53b-c49e0acc7380'	System	05 Oct 2020 21:15:18
User entered 'None (0)'	System	05 Oct 2020 21:15:18

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:15:05', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f976334-6802-40ba-a53b-c49e0acc7380'	System	05 Oct 2020 21:15:18
User entered 'None (0)'	System	05 Oct 2020 21:15:18

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:15:06', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f976334-6802-40ba-a53b-c49e0acc7380'	System	05 Oct 2020 21:15:18
User entered 'None (0)'	System	05 Oct 2020 21:15:18

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:15:08', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f976334-6802-40ba-a53b-c49e0acc7380'	System	05 Oct 2020 21:15:18
User entered 'None (0)'	System	05 Oct 2020 21:15:18

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:15:09', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f976334-6802-40ba-a53b-c49e0acc7380'	System	05 Oct 2020 21:15:18
User entered 'None (0)'	System	05 Oct 2020 21:15:18

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:15:11', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f976334-6802-40ba-a53b-c49e0acc7380'	System	05 Oct 2020 21:15:18
User entered 'None (0)'	System	05 Oct 2020 21:15:18

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:15:12', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f976334-6802-40ba-a53b-c49e0acc7380'	System	05 Oct 2020 21:15:18
User entered 'No (N)'	System	05 Oct 2020 21:15:18

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:15:15', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f976334-6802-40ba-a53b-c49e0acc7380'	System	05 Oct 2020 21:15:18
User entered '05 Oct 2020 16:15'	System	05 Oct 2020 21:15:18

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 5'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:39', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2c3acfda-5db8-4f0e-8759-fce22aa2e0a7'	System	06 Oct 2020 23:49:53
User entered 'None (0)'	System	06 Oct 2020 23:49:53

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:41', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2c3acfda-5db8-4f0e-8759-fce22aa2e0a7'	System	06 Oct 2020 23:49:53
User entered 'None (0)'	System	06 Oct 2020 23:49:53

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:42', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2c3acfda-5db8-4f0e-8759-fce22aa2e0a7'	System	06 Oct 2020 23:49:53
User entered 'None (0)'	System	06 Oct 2020 23:49:53

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:43', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2c3acfda-5db8-4f0e-8759-fce22aa2e0a7'	System	06 Oct 2020 23:49:53
User entered 'None (0)'	System	06 Oct 2020 23:49:53

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:44', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2c3acfda-5db8-4f0e-8759-fce22aa2e0a7'	System	06 Oct 2020 23:49:53
User entered 'None (0)'	System	06 Oct 2020 23:49:53

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:45', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2c3acfda-5db8-4f0e-8759-fce22aa2e0a7'	System	06 Oct 2020 23:49:53
User entered 'None (0)'	System	06 Oct 2020 23:49:53

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:47', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2c3acfda-5db8-4f0e-8759-fce22aa2e0a7'	System	06 Oct 2020 23:49:53
User entered 'No (N)'	System	06 Oct 2020 23:49:53

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:49', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2c3acfda-5db8-4f0e-8759-fce22aa2e0a7'	System	06 Oct 2020 23:49:53
User entered '06 Oct 2020 18:49'	System	06 Oct 2020 23:49:53

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 6'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:19', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '890ce06a-db1b-4df1-a8b1-b597084b0bd4'	System	08 Oct 2020 01:51:37
User entered 'None (0)'	System	08 Oct 2020 01:51:37

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:21', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '890ce06a-db1b-4df1-a8b1-b597084b0bd4'	System	08 Oct 2020 01:51:37
User entered 'None (0)'	System	08 Oct 2020 01:51:37

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:22', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '890ce06a-db1b-4df1-a8b1-b597084b0bd4'	System	08 Oct 2020 01:51:37
User entered 'None (0)'	System	08 Oct 2020 01:51:37

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:23', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '890ce06a-db1b-4df1-a8b1-b597084b0bd4' User entered 'None (0)'	System	08 Oct 2020 01:51:37
	System	08 Oct 2020 01:51:37

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:24', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '890ce06a-db1b-4df1-a8b1-b597084b0bd4'	System	08 Oct 2020 01:51:37
User entered 'None (0)'	System	08 Oct 2020 01:51:37

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:26', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '890ce06a-db1b-4df1-a8b1-b597084b0bd4' User entered 'None (0)'	System	08 Oct 2020 01:51:37

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:28', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '890ce06a-db1b-4df1-a8b1-b597084b0bd4' User entered 'No (N)'	System	08 Oct 2020 01:51:37

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:30', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '890ce06a-db1b-4df1-a8b1-b597084b0bd4' User entered '07 Oct 2020 20:51'	System	08 Oct 2020 01:51:37
	System	08 Oct 2020 01:51:37

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 7'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:30', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4d7e9be5-bc77-4dca-996b-53060c495a78'	System	08 Oct 2020 23:45:42
User entered 'None (0)'	System	08 Oct 2020 23:45:42

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:31', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4d7e9be5-bc77-4dca-996b-53060c495a78'	System	08 Oct 2020 23:45:42
User entered 'None (0)'	System	08 Oct 2020 23:45:42

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:32', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4d7e9be5-bc77-4dca-996b-53060c495a78'	System	08 Oct 2020 23:45:42
User entered 'None (0)'	System	08 Oct 2020 23:45:42

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:33', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4d7e9be5-bc77-4dca-996b-53060c495a78'	System	08 Oct 2020 23:45:42
User entered 'None (0)'	System	08 Oct 2020 23:45:42

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:35', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4d7e9be5-bc77-4dca-996b-53060c495a78'	System	08 Oct 2020 23:45:42
User entered 'None (0)'	System	08 Oct 2020 23:45:42

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:37', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4d7e9be5-bc77-4dca-996b-53060c495a78' User entered 'None (0)'	System	08 Oct 2020 23:45:42
	System	08 Oct 2020 23:45:42

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:38', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4d7e9be5-bc77-4dca-996b-53060c495a78'	System	08 Oct 2020 23:45:42
User entered 'No (N)'	System	08 Oct 2020 23:45:42

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:40', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4d7e9be5-bc77-4dca-996b-53060c495a78' User entered '08 Oct 2020 18:45'	System	08 Oct 2020 23:45:42

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

US3492078

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Michelle Agnoli (b) (4) (b) (4)	09 Oct 2020 21:10:05

US3492078

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020'	Michelle Agnoli (b) (4) (b) (4)	09 Oct 2020 21:10:05

US3492078

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Michelle Agnoli (b) (4)	09 Oct 2020 21:10:05

US3492078

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Michelle Agnoli (b) (4) (b) (4)	09 Oct 2020 21:10:05

US3492078

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Michelle Agnoli (b) (4) (b) (4)	09 Oct 2020 21:10:12

US3492078

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 21:10:12

US3492078

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:54:40

US3492078

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:54:40

US3492078

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:54:40

US3492078

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:54:40

US3492078

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:55:25

US3492078

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 15:55:25

US3492078

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	26 Oct 2020 14:57:08

US3492078

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Lorna Sanchez McCann (b) (4)	26 Oct 2020 14:57:08

US3492078

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Lorna Sanchez McCann (b) (4)	26 Oct 2020 14:57:08

US3492078

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Lorna Sanchez McCann (b) (4)	26 Oct 2020 14:57:08

US3492078

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	26 Oct 2020 14:56:54

US3492078

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 14:56:54

US3492078

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 21:54:12

US3492078

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '06 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 21:54:12

US3492078

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Nov 2020 21:54:12

US3492078

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:11

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	06 Nov 2020 21:54:12

US3492078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 21:54:48

US3492078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 21:54:48

US3492078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '15:15'	(b) (4), (b) (6)	06 Nov 2020 21:54:48

US3492078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '06 Nov 2020 15:15'	System	06 Nov 2020 21:54:48

US3492078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.4' C	(b) (4), (b) (6)	06 Nov 2020 21:54:48

US3492078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	06 Nov 2020 21:54:48

US3492078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'tympanic'	(b) (4), (b) (6)	06 Nov 2020 21:54:48

US3492078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '78'	(b) (4), (b) (6)	06 Nov 2020 21:54:48

US3492078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Nov 2020 21:54:48

US3492078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '20'	(b) (4), (b) (6)	06 Nov 2020 21:54:48

US3492078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Nov 2020 21:54:48

US3492078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '116'	(b) (4), (b) (6)	06 Nov 2020 21:54:48

US3492078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Nov 2020 21:54:48

US3492078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '66'	(b) (4), (b) (6)	06 Nov 2020 21:54:48

US3492078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Nov 2020 21:54:48

US3492078

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 21:54:56

US3492078

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 21:54:56

US3492078

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 21:55:08

US3492078

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 21:55:08

US3492078

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '15:26'	(b) (4), (b) (6)	06 Nov 2020 21:55:08

US3492078

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '06 Nov 2020 15:26'	System	06 Nov 2020 21:55:08

US3492078

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 21:55:12

US3492078

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 21:55:12

US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 64'	System	08 Sep 2020 15:10:36

US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-11-08T18:01:07', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '21f48897-eea1-4b88-8213-2635b545bebb'	System	09 Nov 2020 00:01:18
User entered 'No (N)'	System	09 Nov 2020 00:01:18

US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-11-08T18:01:09', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '21f48897-eea1-4b88-8213-2635b545bebb'	System	09 Nov 2020 00:01:18
User entered 'No (N)'	System	09 Nov 2020 00:01:18

US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-11-08T18:01:13', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '21f48897-eea1-4b88-8213-2635b545bebb' User entered '08 Nov 2020 18:01:13'	System	09 Nov 2020 00:01:18
	System	09 Nov 2020 00:01:18

US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered '05 Nov 2020 00:01'	System	08 Sep 2020 15:10:36

US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 15:10:36
User entered '09 Nov 2020 23:59'	System	08 Sep 2020 15:10:36

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '02 Nov 2020 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '06 Nov 2020 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '09 Nov 2020 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '13 Nov 2020 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '16 Nov 2020 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '20 Nov 2020 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 05:47:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '31 Oct 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '04 Nov 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '07 Nov 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '11 Nov 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:29:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Michelle Agnoli (b) (4)	09 Oct 2020 21:22:54

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[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 pain, LLT: Pain injection site - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 18:30:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 18:30:43
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 19:42:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 19:42:34
Data point term sent to Coder	System	19 Oct 2020 19:41:15
User entered 'Soreness at injection site'	Andrea Wendrow (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, there is no corresponding eDiary data recorded for this symptom on the given date. Please confirm if this is verbally reported and note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:36:09
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, there is no corresponding eDiary data recorded for this symptom on the given date. Please confirm if this is verbally reported and note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification. ' answered with 'patient verbally notified site of soreness at injection site' (Site from DM).	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:18:23
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, there is no corresponding eDiary data recorded for this symptom on the given date. Please confirm if this is verbally reported and note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 01:26:51
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Andrea Wendrow (b) (4)	19 Oct 2020 19:40:50
	(b) (4)	

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '17:00'	Andrea Wendrow (b) (4)	19 Oct 2020 19:40:50
	(b) (4)	

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Sep 2020 17:00'	System	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '7 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 19:42:44
User entered '12:00' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	19 Oct 2020 19:42:44
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 19:40:50
User entered empty.	Andrea Wendrow (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '7 Sep 2020 12:00'	System	19 Oct 2020 19:42:44
User entered empty.	System	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4)	19 Oct 2020 19:40:50
	(b) (4)	

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4)	19 Oct 2020 19:40:50
	(b) (4)	

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Andrea Wendrow (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Andrea Wendrow (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[None](#)

Audit	User	Time (GMT)
User entered '1'	Andrea Wendrow (b) (4)	19 Oct 2020 19:40:50
	(b) (4)	

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andrea Wendrow (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SOLICITED AE BUT COULD NOT GET EPRO TO WORK DESPITE CALLS TO MEDIDATA HELPDESK-Correction-NOT SOLICITED since not captured on diary and reported verbally to site' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	13 Nov 2020 21:19:19
User entered 'solicited AE but could not get ePRO to work despite calls to Medidata helpdesk'	Andrea Wendrow (b) (4)	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Oct 2020 19:40:50

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 14:23:47
User entered 'USA-US101-2020-mRNA-1273-P301000006'	System	23 Nov 2020 14:23:42
User entered 'New'	(b) (4), (b) (6)	23 Nov 2020 14:23:42

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular haemorrhagic disorders, HLT: Haemorrhages NEC, PT: Haematoma, LLT: Hematoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 12:26:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 12:26:00
Data point term sent to Coder	System	20 Nov 2020 23:35:39
Coding entries removed.	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 23:34:45
User entered 'Hematoma of the R leg' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 23:34:45
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: Unilateral leg pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:06:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:06:30
Data point term sent to Coder	System	06 Nov 2020 21:57:07
User entered 'right upper leg pain'	(b) (4), (b) (6) (b) (4)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Andrea Wendrow (b) (4)	20 Nov 2020 23:34:45
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered '03 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Andrea Wendrow (b) (4)	20 Nov 2020 22:42:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	20 Nov 2020 22:46:22
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	20 Nov 2020 22:46:22
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	20 Nov 2020 22:42:49
User entered '11 Nov 2020' reason for change: New Information	Andrea Wendrow (b) (4)	20 Nov 2020 22:42:49
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: New Information	Andrea Wendrow (b) (4)	20 Nov 2020 23:34:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Andrea Wendrow (b) (4)	20 Nov 2020 23:34:45
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1' reason for change: New Information	Andrea Wendrow (b) (4)	20 Nov 2020 23:34:45
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020' reason for change: New Information	Andrea Wendrow (b) (4)	20 Nov 2020 23:34:45
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Nov 2020' reason for change: New Information	Andrea Wendrow (b) (4)	20 Nov 2020 23:34:45
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Andrea Wendrow (b) (4)	20 Nov 2020 23:34:45
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Andrea Wendrow (b) (4)	20 Nov 2020 23:34:45
reason for change: Data Entry Error	(b) (4)	
User entered 'None (NONE)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[None](#)

Audit	User	Time (GMT)
User entered '0' reason for change: New Information	Andrea Wendrow (b) (4)	20 Nov 2020 23:34:45
User entered '1'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1' reason for change: New Information	Andrea Wendrow (b) (4)	20 Nov 2020 23:34:45
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1' reason for change: New Information	Andrea Wendrow (b) (4)	20 Nov 2020 23:34:45
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Andrea Wendrow (b) (4)	20 Nov 2020 23:34:45
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	Andrea Wendrow (b) (4)	20 Nov 2020 22:46:22
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	20 Nov 2020 23:34:45
User entered 'hematoma of the right leg' reason for change: New Information	Andrea Wendrow (b) (4)	20 Nov 2020 22:46:22
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT WAS WORKING OUT ON TOTAL GYM MACHINE AND INJURED RIGHT UPPER LEG MUSCLE. ROM AND STRENGTH WITHIN NORMAL LIMITS AND BASELINE FOR PARTICIPANT. Subject hospitalized 11Nov 2020 through 17Nov2020 for pain and swelling in R leg. Work up included RLE CT which showed large intramuscular hematoma of the vastus lateralis with multiple foci of active extravasation from branches of the profunda femoral artery. No DVT. Apixaban held and ASA discontinued. Colonoscopy performed for signs of bleeding and complaint of intermittent diarrhea that he did not report at D57 nor on diary or safety calls. Over course of admission received 3 units PRBCs. Vascular angiogram and embolization performed on 13Nov2020. At discharge apixaban restarted at 2.5mg bid' reason for change: New Information	Andrea Wendrow (b) (4)	20 Nov 2020 23:34:45
User entered 'Participant was working out on total gym machine and injured right upper leg muscle. ROM and strength within normal limits and baseline for participant.'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 23:34:45
User entered '0'	System	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 23:34:45
User entered '0'	System	06 Nov 2020 21:56:46

US3492078

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Nov 2020 23:34:45

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:29:11

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:20:01

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 20:22:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 20:22:44
Data point term sent to Coder	System	05 Sep 2020 20:22:08
User entered 'Aspirin'	Marla Schwarber (b) (4)	05 Sep 2020 20:21:20

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

[Indication](#)

Audit	User	Time (GMT)
User entered 'Coronary artery disease'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 20:21:20

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 20:21:20

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 20:21:20

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

[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, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 20:24:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 20:24:45
Data point term sent to Coder	System	05 Sep 2020 20:24:10
User entered 'Eliquis'	Marla Schwarber (b) (4)	05 Sep 2020 20:23:34

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

[Indication](#)

Audit	User	Time (GMT)
User entered 'Cerebrovascular disease'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 20:23:34

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 20:23:34

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 20:23:34

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:25:46
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 Sep 2020 20:25:46
Data point term sent to Coder	System	05 Sep 2020 20:25:11
User entered 'Lasix'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

[Indication](#)

Audit	User	Time (GMT)
User entered 'Congestive heart failure'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 20:24:46

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 20:24:46

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 20:24:46

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:27:46
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 Sep 2020 20:27:46
Data point term sent to Coder	System	05 Sep 2020 20:26:12
User entered 'Atorvastatin'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM Re-Query: The start date of HYPERLIPIDEMIA is 2003 which is prior to the condition reported in medical History form. Please reconcile. Thank you!' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 15:29:26
Query 'Per DM Re-Query: The start date of HYPERLIPIDEMIA is 2003 which is prior to the condition reported in medical History form. Please reconcile. Thank you!' answered with 'corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	09 Nov 2020 19:33:59
User opened query 'Per DM Re-Query: The start date of HYPERLIPIDEMIA is 2003 which is prior to the condition reported in medical History form. Please reconcile. Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:24:32
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:24:32
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. (Site from DM).	Michelle Agnoli (b) (4) (b) (4)	23 Oct 2020 21:27:39
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:20:45
User entered 'Hyperlipidemia'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2003'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 20:26:03

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 20:26:03

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 20:26:03

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:30:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:30:42
Data point term sent to Coder Coding entries removed.	System Michelle Agnoli (b) (4) (b) (4)	23 Oct 2020 21:29:32 23 Oct 2020 21:28:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 05:48:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 05:48:46
Data point term sent to Coder User entered 'Metoprolol'	System Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:13 05 Sep 2020 20:27:17

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:27:22
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'completed' (Site from DM).	Michelle Agnoli (b) (4)	23 Oct 2020 21:28:59
User entered 'atrial fibrillation' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	23 Oct 2020 21:28:50
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:20:58
User entered 'Heart rate control'	Marla Schwarber (b) (4)	05 Sep 2020 20:27:17

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 20:27:17

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 20:27:17

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 20:27:17

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 20:29:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 20:29:46
Data point term sent to Coder	System	05 Sep 2020 20:29:13
User entered 'Sertraline'	Marla Schwarber (b) (4)	05 Sep 2020 20:28:25

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

[Indication](#)

Audit	User	Time (GMT)
User entered 'Depression'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 20:28:25

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 20:28:25

US3492078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 20:28:25

US3492078

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:29:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Marla Schwarber (b) (4)	04 Nov 2020 20:19:09
User entered 'Yes (Y)'	Marla Schwarber (b) (4)	08 Sep 2020 14:42:08

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'USA-US101-2020-MRNA-1273-P301000006'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Yes (Y)'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Yes (Y)'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Richard'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Novak'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered '808 S. Wood St'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Chicago'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'IL'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered '60612'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	23 Nov 2020 20:08:16

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 20:08:16

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'USA-US101-2020-MRNA-1273-P301000006'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Yes (Y)'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Yes (Y)'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Richard'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Novak'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered '808 S. Wood St'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Chicago'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'IL'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered '60612'	System	23 Nov 2020 14:23:42

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

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[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	23 Nov 2020 20:08:16

US3492078

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 20:08:16

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:29:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '23/Nov/2020 20:08'	System	23 Nov 2020 20:08:16

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

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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)	23 Nov 2020 20:08:16