

US3672278 (Prod: Coastal Carolina Research Center)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:10:47

All time stamps listed in this document are displayed in GMT

US3672278

Form: Participant Creation

Generated On: 26 Nov 2020 11:10:47

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:47

Date of Birth (MMM yyyy)	(b) (6) 1942
Age	78
Age Units	YEARS
Age (Derived)	78
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:47

Date of Informed Consent (<i>dd MMM yyyy</i>)	24 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:10:47

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:10:47

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:47

Condition	MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	UN UNK 1989
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1989
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1989
Start Year (derived)	1989
Stop Month and Year (derived)	JAN 1989
Stop Year (derived)	1989

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:47

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:47

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

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:47

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:47

Condition	DEFIBRILLATOR IMPLANT
Start date (dd MMM yyyy)	UN DEC 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)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:47

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN DEC 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)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:47

Condition	CONGESTIVE HEART FAILURE
Start date (dd MMM yyyy)	UN DEC 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)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:47

Condition	CEREBRAL VASCULAR DISEASE
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:10:47

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	24 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:15 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 14:15
Height (<i>xxx.x</i>)	177.5 cm
Weight (<i>xxx.x</i>)	95.2 kg
BMI (<i>xxx.x</i>)	30.21623 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	ND - Not Done
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

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)	True

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Folder: Screening

Form: Risk of Exposure

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	True
Specify	RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION.

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:10:47

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 188656

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:10:47

Height	177.5 cm
Weight	96.8 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

Height	177.5 cm
Weight	96.8 kg
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	10:32 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 10:32
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

Height	177.5 cm
Weight	96.8 kg
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	12:04 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 12:04
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	91 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

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)	31 AUG 2020
What was the treatment time? (00:00-23:59)	11:25 (24 HR)
Treatment Date and Time (derived)	31 AUG 2020 11:25
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 AUG 2020

Collection time (00:00-23:59)

11:07 (24 HR)

Collection date and time (derived)

31 AUG 2020 11:07

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:10:47

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:49	31 AUG 2020 10:49
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

31 AUG 2020 11:58

PC Open Date & Time

31 AUG 2020 11:45

PC Close Date & Time

31 AUG 2020 14:15

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

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 96.7 °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	01 SEP 2020 00:04
PC Open Date & Time	31 AUG 2020 15:10
PC Close Date & Time	01 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °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

01 SEP 2020 22:58

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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 SEP 2020 00:03

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 23:38

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 22:56

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °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 SEP 2020 23:13

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 23:10

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

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)**

4

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 - **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

31 AUG 2020 12:00

PC Open Date & Time

31 AUG 2020 11:45

PC Close Date & Time

31 AUG 2020 14:15

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

2

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 - **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

01 SEP 2020 00:05

PC Open Date & Time

31 AUG 2020 15:10

PC Close Date & Time

01 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:10:47

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

01 SEP 2020 22:59

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:10:47

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

03 SEP 2020 00:03

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 23:39

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:10:47

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

04 SEP 2020 22:56

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:10:47

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

05 SEP 2020 23:14

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:10:47

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

06 SEP 2020 23:10

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 12:02
PC Open Date & Time	31 AUG 2020 11:45
PC Close Date & Time	31 AUG 2020 14:15

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 00:04

PC Open Date & Time	31 AUG 2020 15:10

PC Close Date & Time	01 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:47

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 ☒

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:47

Yes ☐	
PC Time stamp	01 SEP 2020 23:01
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:47

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 ☒

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:47

Yes ☐	
PC Time stamp	03 SEP 2020 00:04
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:47

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 ☒

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:47

Yes ☐	
PC Time stamp	03 SEP 2020 23:40
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:47

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 ☒

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:47

Yes ☐	
PC Time stamp	04 SEP 2020 22:57
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:47

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 ☒

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:47

Yes ☐	
PC Time stamp	05 SEP 2020 23:15
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:47

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 ☒

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:47

Yes ☐	
PC Time stamp	06 SEP 2020 23:11
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3672278

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672278

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

Was Contact Attempted?

Yes ☒

No ☐

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

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672278

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

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

US3672278

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	10:16 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 10:16
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

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

US3672278

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3672278

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:47

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	28 SEP 2020
Collection time (<i>00:00-23:59</i>)	10:43 (24 HR)
Collection date and time (derived)	28 SEP 2020 10:43

US3672278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:10:47

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:30	28 SEP 2020 10:30
Nasopharyngeal Swab 2	No		

US3672278

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672278

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672278

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

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

US3672278

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	23 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:07 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 10:07
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	79 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	54 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672278

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:47

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3672278

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

10:15 (24 HR)

Collection date and time (derived)

23 OCT 2020 10:15

US3672278

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

31 OCT 2020 19:04:00

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 NOV 2020 18:09:54
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 NOV 2020 23:29:50
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2020 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2020 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2020 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2020 00:01

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13 DEC 2020 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

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03 JAN 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

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10 JAN 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

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17 JAN 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

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24 JAN 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2021 00:01

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31 JAN 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

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07 FEB 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2021 00:01

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14 FEB 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2021 00:01

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21 FEB 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2021 00:01

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07 MAR 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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14 MAR 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 JUL 2021 00:01

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25 JUL 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

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15 AUG 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

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22 AUG 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

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12 SEP 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

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19 SEP 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 JAN 2022 00:01

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23 JAN 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 JAN 2022 00:01

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30 JAN 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 FEB 2022 00:01

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06 FEB 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 FEB 2022 00:01

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13 FEB 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 FEB 2022 00:01

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20 FEB 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 FEB 2022 00:01

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27 FEB 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 MAR 2022 00:01

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06 MAR 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 MAR 2022 00:01

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13 MAR 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 MAR 2022 00:01

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20 MAR 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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23 MAR 2022 00:01

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27 MAR 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 APR 2022 00:01

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17 APR 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 APR 2022 00:01

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24 APR 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 APR 2022 00:01

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01 MAY 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 MAY 2022 00:01

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08 MAY 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 MAY 2022 00:01

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15 MAY 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

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25 MAY 2022 00:01

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29 MAY 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 JUN 2022 00:01

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05 JUN 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 JUN 2022 00:01

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12 JUN 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 JUN 2022 00:01

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19 JUN 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 JUN 2022 00:01

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26 JUN 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

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03 JUL 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

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06 JUL 2022 00:01

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10 JUL 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

Date and time of submission

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31 JUL 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

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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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

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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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

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Folder: New Safety Follow Up Diary (1)

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

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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

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02 OCT 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3672278

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672278

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

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

US3672278

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3672278

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:10:47

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3672278

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:10:47

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

AEID	USA-US116-2020-MRNA-1273-P30 1000001
Adverse event	ISCHEMIC STROKE (FRONTAL LOBE)
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)	10 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	11 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	11 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

309 of 1744

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

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

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

SUBJECT IS A 78 YEAR OLD
MAKE WITH HISTORY OF CVD,
CAD, CHF, AND DM. DAY 8
PHONE CALL WAS MADE ON
9/11/2020 AND WAS MOSTLY
COMPLETED WITH SUBJECT'S
WIFE. SUBJECT'S WIFE
REPORTS ON 9/10/2020. SUBJECT
DEVELOPED INABILITY TO
SPEAK. HE WAS ADMITTED TO
THE HOSPITAL AND
DIAGNOSED WITH FRONTAL
LOBE STROKE. SUBJECT WAS
DISCHARGED 9/11/2020 WITH
ONGOING SPEECH DEFICIT. HE
WAS STARTED ON PLAVIX AND
WILL BE STARTING SPEECH
THERAPY. MEDICAL RECORDS
WERE RECEIVED WHICH
INCLUDED LAB RESULTS AND
DIAGNOSTIC TEST RESULTS.
RELEVANT OR ABNORMAL
LAB TESTS INCLUDE: PTT 28.7
SEC, PT 13.4 SEC, INR 1.0,
HGA1C 7.7%. FINDINGS FROM
NONCONTRAST BRAIN CT
SCAN ON 09/10/20 @ 1538
INLCUDE SMALL EVOLVING
ACUTE INFARCTIONS IN THE
LEFT INSULAR CORTEX AND
ANTERIOR LEFT CORONA
RADIATA, AND NO
HEMORRHAGE. ULTRASOUND
CAROTID DUPLEX BILATERAL
COMPLETED ON 09/10/20 @ 1840
SHOWED NO STENOSIS
BILATERALLY.

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

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

AEID	USA-US116-2020-MRNA-1273-P30 1000001
Adverse event	SPEECH DEFICIT
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)	10 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
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)	10 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	11 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102) 312 of 1744

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

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

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

SUBJECT IS A 78 YEAR OLD
MAKE WITH HISTORY OF CVD,
CAD, CHF, AND DM. DAY 8
PHONE CALL WAS MADE ON
9/11/2020 AND WAS MOSTLY
COMPLETED WITH SUBJECT'S
WIFE. SUBJECT'S WIFE
REPORTS ON 9/10/2020. SUBJECT
DEVELOPED INABILITY TO
SPEAK. HE WAS ADMITTED TO
THE HOSPITAL AND
DIAGNOSED WITH FRONTAL
LOBE STROKE. SUBJECT WAS
DISCHARGED 9/11/2020 WITH
ONGOING SPEECH DEFICIT. HE
WAS STARTED ON PLAVIX AND
WILL BE STARTING SPEECH
THERAPY. MEDICAL RECORDS
WERE RECEIVED WHICH
INCLUDED LAB RESULTS AND
DIAGNOSTIC TEST RESULTS.
RELEVANT OR ABNORMAL
LAB TESTS INCLUDE: PTT 28.7
SEC, PT 13.4 SEC, INR 1.0,
HGA1C 7.7%. FINDINGS FROM
NONCONTRAST BRAIN CT
SCAN ON 09/10/20 @ 1538
INLCUDE SMALL EVOLVING
ACUTE INFARCTIONS IN THE
LEFT INSULAR CORTEX AND
ANTERIOR LEFT CORONA
RADIATA, AND NO
HEMORRHAGE. ULTRASOUND
CAROTID DUPLEX BILATERAL
COMPLETED ON 09/10/20 @ 1840
SHOWED NO STENOSIS
BILATERALLY.

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

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:10:47

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

Yes ☒

No ☐

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

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

Name of Medication	METOPROLOL
Prophylaxis	Yes ☐ No ☒
Indication	MYOCARDIAL INFARCTION
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 ☐

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

	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 1989
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	☒

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

Name of Medication	LORATADINE
Prophylaxis	Yes ☐ No ☒
Indication	ALLERGIC RHINITIS
Dose per administration	10
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 ☐

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

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

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

Name of Medication	ASPIRIN
Prophylaxis	Yes ☒ No ☐
Indication	MYOCARDIAL INFARCTION
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 ☐

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK	2000
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	11 SEP	2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

Name of Medication	BENADRYL
Prophylaxis	Yes ☐ No ☒
Indication	LEG CRAMPS (BILATERAL)
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 ☐

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

Name of Medication	SPIRNOLACTONE
Prophylaxis	Yes ☐ No ☒
Indication	MYOCARDIAL INFARCTION
Dose per administration	12.5
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 ☐

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

	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	☒

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

Name of Medication	GLIPIZIDE
Prophylaxis	Yes ☐ No ☒
Indication	TYPE II DIABETES
Dose per administration	10
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 ☐

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

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 2014
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 ☒

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

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

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

	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 1989	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	10 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

Name of Medication	LASIX
Prophylaxis	Yes ☐ No ☒
Indication	MYCARDIAL INFARCTION
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 ☐

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

	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 1989
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	☒

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

Name of Medication	METFORMIN
Prophylaxis	Yes ☐ No ☒
Indication	TYPE 2 DM
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

	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 2014
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	☒

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

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

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		11 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify		IM
Start date (dd MMM yyyy)		04 OCT 2020
Start date completely unknown		False
Ongoing?		Yes ☐
		No ☒
If not Ongoing, End date (dd MMM yyyy)		04 OCT 2020
Was this medication taken for solicited event?		Yes ☐
		No ☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☒

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

Name of Medication	LOSARTAN
Prophylaxis	Yes ☒ No ☐
Indication	MYOCARDIAL INFARCTION
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 ☐

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		11 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ☒
Indication	FRONTAL LOBE STROKE
Dose per administration	325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

	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)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		10 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

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

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

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

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

Name of Medication	PRAVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	FRONTAL LOBE STROKE
Dose per administration	80
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 ☐

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

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

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

Name of Medication	METFORMIN
Prophylaxis	Yes ☐ No ☒
Indication	TYPE 2 DIABETES
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

	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 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☒	No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:10:47

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3672278

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:10:47

Date of dosing discontinuation (dd MMM yyyy)

28 SEP 2020

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☒

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

AE#1

US3672278

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:10:47

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 ☐

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

SAEID	USA-US116-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☒ No ☐
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	1156 BOWMAN ROAD
Site Address: City	MOUNT PLEASANT
Site Address: State	SOUTH CAROLINA
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:10:47

SAEID	USA-US116-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☒ No ☐
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	1156 BOWMAN ROAD
Site Address: City	MOUNT PLEASANT
Site Address: State	SOUTH CAROLINA
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/SEP/2020 15:21
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

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:10:47

SAEID	USA-US116-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☒ No ☐
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	1156 BOWMAN ROAD
Site Address: City	MOUNT PLEASANT
Site Address: State	SOUTH CAROLINA
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/OCT/2020 16:30
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

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:10:47

SAEID	USA-US116-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☒ No ☐
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	1156 BOWMAN ROAD
Site Address: City	MOUNT PLEASANT
Site Address: State	SOUTH CAROLINA
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	28/OCT/2020 15:04
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

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:10:47

SAEID	USA-US116-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☒ No ☐
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	1156 BOWMAN ROAD
Site Address: City	MOUNT PLEASANT
Site Address: State	SOUTH CAROLINA
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/NOV/2020 17:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:10:47

SAEID	USA-US116-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☒ No ☐
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	1156 BOWMAN ROAD
Site Address: City	MOUNT PLEASANT
Site Address: State	SOUTH CAROLINA
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/NOV/2020 18:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3672278 (Prod: Coastal Carolina Research Center)

US3672278

Form: Participant Creation

Generated On: 26 Nov 2020 11:10:47

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:12:46
User entered 'US3672278'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:09:22

US3672278

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:12:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:41:59

US3672278

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:12:51
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:09:23

US3672278

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:12:51
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Aug 2020 18:41:59

US3672278

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	25 Aug 2020 18:41:59

US3672278

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered (b) (6) 1942'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:09:24

US3672278

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:47

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered '78'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

US3672278

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:47

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	25 Aug 2020 18:42:18

US3672278

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:47

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '78'	System	25 Aug 2020 18:44:05

US3672278

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:47

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered 'Male (M)'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

US3672278

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:47

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

US3672278

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:47

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered '1'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

US3672278

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:47

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

US3672278

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:47

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

US3672278

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:47

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

US3672278

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:47

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

US3672278

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:47

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

US3672278

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:47

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:42:18

US3672278

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:47

Unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

US3672278

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:10:47

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

US3672278

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:32
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 18:44:05

US3672278

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	25 Aug 2020 18:44:05

US3672278

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '2020'	System	25 Aug 2020 18:44:05

US3672278

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:47

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:32
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 18:47:29
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	25 Aug 2020 18:44:05

US3672278

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:44:05

US3672278

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:32
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:44:05

US3672278

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:47

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:32
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:44:05

US3672278

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:47

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:32
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:44:05

US3672278

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:47

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:32
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:09:23

US3672278

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:10:47

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 18:44:20

US3672278

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:15:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:44:20

US3672278

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:10:47

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User closed query 'Please update MH page. Thanks' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 16:02:46
Query 'Please update MH page. Thanks' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 16:02:16
User opened query 'Please update MH page. Thanks' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 12:20:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:15:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:47:13

US3672278

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:47

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Please update page per Med Hx report. Thanks' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:54:55
Query 'Please update page per Med Hx report. Thanks' answered with 'Updated per source.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 18:34:10
User opened query 'Please update page per Med Hx report. Thanks' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 13:59:16
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:49:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 18:49:31
Data point term sent to Coder	System	25 Aug 2020 18:49:06
User entered 'Myocardial infarction'	(b) (4), (b) (6)	25 Aug 2020 18:48:12

US3672278

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'un UNK 1989'	(b) (4), (b) (6)	25 Aug 2020 18:48:12

US3672278

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:48:12

US3672278

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:54:44
User closed query 'Per source, this is not ongoing. End date is UN/UNK/1989. Please verify and update. Thanks!' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:54:41
Query 'Per source, this is not ongoing. End date is UN/UNK/1989. Please verify and update. Thanks!' answered with 'Updated per source' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 18:33:57
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:33:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:33:30
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User opened query 'Per source, this is not ongoing. End date is UN/UNK/1989. Please verify and update. Thanks!' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 12:16:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:48:12

US3672278

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User closed query 'Per MM, please provide the end date ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:35:34
Query 'Per MM, please provide the end date ' answered with 'Updated per source.' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 15:54:39
User entered 'un UNK 1989' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:34:03
User opened query 'Per MM, please provide the end date ' (Site from DM). User entered empty.	(b) (4), (b) (6)	21 Oct 2020 18:33:30
	(b) (4), (b) (6)	21 Oct 2020 18:33:30
	(b) (4), (b) (6)	22 Sep 2020 12:16:49
	(b) (4), (b) (6)	21 Sep 2020 19:53:50
	(b) (4), (b) (6)	25 Aug 2020 18:48:12

US3672278

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:48:12

US3672278

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Jan 1989'	System	25 Aug 2020 18:48:12

US3672278

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '1989'	System	25 Aug 2020 18:48:12

US3672278

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Jan 1989'	System	21 Oct 2020 18:33:30
User entered empty.	System	25 Aug 2020 18:48:12

US3672278

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '1989'	System	21 Oct 2020 18:33:30
User entered empty.	System	25 Aug 2020 18:48:12

US3672278

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:47

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:52:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:52:39
Data point term sent to Coder	System	25 Aug 2020 18:51:13
User entered 'Type 2 Diabetes'	(b) (4), (b) (6)	25 Aug 2020 18:50:23

US3672278

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'un UNK 2014'	(b) (4), (b) (6)	25 Aug 2020 18:50:23

US3672278

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:50:23

US3672278

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:50:23

US3672278

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:50:23

US3672278

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:50:23

US3672278

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	25 Aug 2020 18:50:23

US3672278

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '2014'	System	25 Aug 2020 18:50:23

US3672278

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 18:50:23

US3672278

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 18:50:23

US3672278

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:47

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Leg cramps - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:52:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:52:39
Data point term sent to Coder	System	25 Aug 2020 18:51:15
User entered 'Leg cramps'	(b) (4), (b) (6)	25 Aug 2020 18:50:40

US3672278

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'un UNK 1990'	(b) (4), (b) (6)	25 Aug 2020 18:50:40

US3672278

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:50:40

US3672278

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:50:40

US3672278

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:50:40

US3672278

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:50:40

US3672278

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	25 Aug 2020 18:50:40

US3672278

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '1990'	System	25 Aug 2020 18:50:40

US3672278

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 18:50:40

US3672278

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 18:50:40

US3672278

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:47

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 18:52:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	25 Aug 2020 18:52:39
Data point term sent to Coder	System	25 Aug 2020 18:51:13
User entered 'allergic rhinitis'	(b) (4), (b) (6)	25 Aug 2020 18:50:54

US3672278

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'un UNK 1989'	(b) (4), (b) (6)	25 Aug 2020 18:50:54

US3672278

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:50:54

US3672278

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:50:54

US3672278

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:50:54

US3672278

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:50:54

US3672278

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Jan 1989'	System	25 Aug 2020 18:50:54

US3672278

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '1989'	System	25 Aug 2020 18:50:54

US3672278

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 18:50:54

US3672278

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 18:50:54

US3672278

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:47

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per MM: Please include the underlying condition that led to the procedure. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:37:10
Query 'Per MM: Please include the underlying condition that led to the procedure. ' answered with 'Underlying Condition listed in MH' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:07:58
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User opened query 'Per MM: Please include the underlying condition that led to the procedure. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 19:55:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Implantable defibrillator insertion, LLT: Implantable defibrillator insertion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:55:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:55:33
Data point term sent to Coder	System	25 Aug 2020 18:54:26
User entered 'DEFIBRILLATOR IMPLANT' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 18:54:11
Data point term sent to Coder	System	25 Aug 2020 18:52:18
User entered 'defibrillator inimplant'	(b) (4), (b) (6)	25 Aug 2020 18:51:24

US3672278

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'un Dec 2019'	(b) (4), (b) (6)	25 Aug 2020 18:51:24

US3672278

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:51:24

US3672278

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:51:24

US3672278

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:51:24

US3672278

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:51:24

US3672278

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Dec 2019'	System	25 Aug 2020 18:51:24

US3672278

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '2019'	System	25 Aug 2020 18:51:24

US3672278

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 18:51:24

US3672278

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 18:51:24

US3672278

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:47

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
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)	25 Aug 2020 18:53:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:53:42
Data point term sent to Coder	System	25 Aug 2020 18:52:19
User entered 'coronary artery disease'	(b) (4), (b) (6)	25 Aug 2020 18:51:53

US3672278

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'un Dec 2019'	(b) (4), (b) (6)	25 Aug 2020 18:51:53

US3672278

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:51:53

US3672278

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:51:53

US3672278

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:51:53

US3672278

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:51:53

US3672278

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Dec 2019'	System	25 Aug 2020 18:51:53

US3672278

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '2019'	System	25 Aug 2020 18:51:53

US3672278

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 18:51:53

US3672278

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 18:51:53

US3672278

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:47

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if corresponding medication is given. Note that there is no Concomitant Medication listed and treatment is typically required for this condition. Reconcile and update as appropriate or comment. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:40:48
Query 'Per DM CLR: Please review if corresponding medication is given. Note that there is no Concomitant Medication listed and treatment is typically required for this condition. Reconcile and update as appropriate or comment. ' answered with 'all conmeds are up to date' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:54:06
User opened query 'Per DM CLR: Please review if corresponding medication is given. Note that there is no Concomitant Medication listed and treatment is typically required for this condition. Reconcile and update as appropriate or comment. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 06:52:17
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:55:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:55:55
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:55:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:55:34
Data point term sent to Coder	System	25 Aug 2020 18:54:25
User entered 'congestive heart failure'	(b) (4), (b) (6)	25 Aug 2020 18:53:26

US3672278

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'un Dec 2019'	(b) (4), (b) (6)	25 Aug 2020 18:53:26

US3672278

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:53:26

US3672278

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:53:26

US3672278

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:53:26

US3672278

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:53:26

US3672278

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Dec 2019'	System	25 Aug 2020 18:53:26

US3672278

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '2019'	System	25 Aug 2020 18:53:26

US3672278

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 18:53:26

US3672278

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 18:53:26

US3672278

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:47

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system vascular disorders NEC, PT: Cerebrovascular disorder, LLT: Cerebrovascular disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 06:09:55
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 06:09:55
Data point term sent to Coder	System	28 Sep 2020 20:22:13
User entered 'cerebral vascular disease'	(b) (4), (b) (6) (b) (4)	28 Sep 2020 20:21:55

US3672278

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'un UNK 2002'	(b) (4), (b) (6)	28 Sep 2020 20:21:55

US3672278

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 20:21:55

US3672278

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 20:21:55

US3672278

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:21:55

US3672278

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 20:21:55

US3672278

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	28 Sep 2020 20:21:55

US3672278

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '2002'	System	28 Sep 2020 20:21:55

US3672278

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 20:21:55

US3672278

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 20:21:55

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered '14:15'	(b) (4), (b) (6)	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 14:15'	System	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered '177.5' cm	(b) (4), (b) (6)	25 Aug 2020 18:54:54
DataPoint set to visible.	System	25 Aug 2020 18:44:20

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered '95.2' kg	(b) (4), (b) (6)	25 Aug 2020 18:54:54
DataPoint set to visible.	System	25 Aug 2020 18:44:20

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '30.21623'	System	17 Sep 2020 00:21:38
User entered '30.2'	System	25 Aug 2020 18:54:54
DataPoint set to visible.	System	25 Aug 2020 18:44:20

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	25 Aug 2020 18:54:54
DataPoint set to visible.	System	25 Aug 2020 18:44:20

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered '97.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:10:48
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered 'Other (Other)'	(b) (4), (b) (6)	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered '72' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:10:48
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:10:48
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered '103' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:10:48
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered '67' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:10:48
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:55:06

US3672278

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:08
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 11:34:25
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		31 Aug 2020 15:03:39
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 18:55:06

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered '1'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered '1'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

[Other](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:10:47

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'Resident in a community with ongoing person to person transmission.'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Please complete the immunogenicity assessment and Central Lab Swab page. Thanks!' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:55:56
Query 'Please complete the immunogenicity assessment and Central Lab Swab page. Thanks!' answered with 'Completed.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 18:41:31
User opened query 'Please complete the immunogenicity assessment and Central Lab Swab page. Thanks!' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 12:41:44
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:30:47
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:03:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 15:03:39
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 15:03:39
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 19:02:28
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:02:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:01:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:55:52

US3672278

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:30:47
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 15:03:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:01:59
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 18:55:52

US3672278

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:30:47
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 15:03:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:01:59
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Aug 2020 18:55:52

US3672278

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	31 Aug 2020 15:03:39
User entered empty.	System	25 Aug 2020 19:02:28
User entered 'VISIT1'	System	25 Aug 2020 18:55:52

US3672278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Please, complete Immunogenicity Assessment, Central Laboratory - Nasopharyngeal Swab as per CCGs. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 12:21:21
Query 'Per CDM: Please, complete Immunogenicity Assessment, Central Laboratory - Nasopharyngeal Swab as per CCGs. Thank you. ' answered with 'Completed.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 18:41:51
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:31:33
User opened query 'Per CDM: Please, complete Immunogenicity Assessment, Central Laboratory - Nasopharyngeal Swab as per CCGs. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 06:25:16
User entered '31 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:04:45

US3672278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:31:33
User entered '188656'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:04:45

US3672278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:31:33
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:04:45

US3672278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:31:33
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 06:45:06
Query 'PER CDM: Please complete this section of the form.' answered with 'PATIENT DOES NOT HAVE CHRONIC LUNG DISEASE. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 18:53:28
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 19:34:01
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:04:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 15:04:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 15:04:04
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 19:02:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:02:12
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:56:08

US3672278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:31:33
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:04:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 15:04:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 15:04:04
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 19:02:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:02:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:56:08

US3672278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:31:33
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:04:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 15:04:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 15:04:04
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 19:02:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:02:12
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:56:08

US3672278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:31:33
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:04:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 15:04:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 15:04:04
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 19:02:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:02:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:56:08

US3672278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:10:47

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:31:33
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:04:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 15:04:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 15:04:04
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 19:02:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:02:12
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:56:08

US3672278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:07:18
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 17:38:19
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:40:16
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:42:33

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:10:47

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '177.5' cm	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:10:47

Weight

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '96.8' kg	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:10:47

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '177.5' cm	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:10:47

Weight

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '96.8' kg	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '10:32'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 10:32'	System	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '98.0' F	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered 'Oral (Oral)'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '60'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '16'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '110'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 05:29:59
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 15:26:02
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:21:38
User entered '58'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:10:47

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '177.5' cm	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:10:47

Weight

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '96.8' kg	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Please complete post-dose information per source. Thanks' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:56:26
Query 'Please complete post-dose information per source. Thanks' answered with 'Completed.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 18:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 18:44:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 18:44:12
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User opened query 'Please complete post-dose information per source. Thanks' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 12:39:21
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:47:34
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User entered '12:04' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:04'	System	21 Oct 2020 18:44:12
User entered empty.	System	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Oct 2020 18:44:29
User entered '97.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:44:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Oct 2020 18:44:12
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User entered '97.7' (non-conformant).	(b) (4), (b) (6)	21 Oct 2020 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User entered '68' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 18:44:12
User entered empty.	System	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Oct 2020 18:44:12
User entered empty.	System	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User entered '91' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 18:44:12
User entered empty.	System	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User entered '64' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 18:44:12
User entered empty.	System	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:39:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 15:47:42

US3672278

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:39:32
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 15:47:42

US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:40:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 15:45:08

US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:40:20
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:45:08

US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:40:20
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:45:08

US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 15:45:08

US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:40:20
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 15:45:08

US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:40:20
User entered '11:25'	(b) (4), (b) (6)	31 Aug 2020 15:45:08

US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:25'	System	31 Aug 2020 15:45:08

US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:40:20
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	31 Aug 2020 15:45:08

US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:40:20
User entered 'ONCE'	System	31 Aug 2020 15:45:08

US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 15:45:08

US3672278

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 18:40:50

US3672278

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	(b) (4), (b) (6)	21 Oct 2020 18:40:50

US3672278

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:07'	(b) (4), (b) (6)	21 Oct 2020 18:40:50

US3672278

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:07'	System	21 Oct 2020 18:40:50

US3672278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:10:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	(b) (4), (b) (6)	21 Oct 2020 18:41:14

US3672278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:10:47

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Oct 2020 18:41:14

US3672278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:10:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 18:41:14

US3672278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:10:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:49'	(b) (4), (b) (6)	21 Oct 2020 18:41:14

US3672278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 10:49'	System	21 Oct 2020 18:41:14

US3672278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:10:47

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Oct 2020 18:41:14

US3672278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:10:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 18:41:14

US3672278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:10:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 18:41:14

US3672278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 18:41:14

US3672278

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:40:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:30:11

US3672278

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:30:11

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T11:57:22', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '5f463ee8-46fc-4c60-8b54-6299f5cbd047'	System	31 Aug 2020 15:58:40
User entered 'Yes (Y)'	System	31 Aug 2020 15:58:40

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T11:57:40', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '5f463ee8-46fc-4c60-8b54-6299f5cbd047'	System	31 Aug 2020 15:58:40
User entered '97.7'	System	31 Aug 2020 15:58:40

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T11:57:49', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '5f463ee8-46fc-4c60-8b54-6299f5cbd047'	System	31 Aug 2020 15:58:40
User entered 'No (N)'	System	31 Aug 2020 15:58:40

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T11:58:03', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '5f463ee8-46fc-4c60-8b54-6299f5cbd047'	System	31 Aug 2020 15:58:40
User entered '31 Aug 2020 11:58'	System	31 Aug 2020 15:58:40

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:45'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 14:15'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:04:29', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'e543a863-4db2-4130-afe1-3b62f90b70b7'	System	01 Sep 2020 04:05:01
User entered 'Yes (Y)'	System	01 Sep 2020 04:05:01

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:04:42', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'e543a863-4db2-4130-afe1-3b62f90b70b7'	System	01 Sep 2020 04:05:01
User entered '96.7'	System	01 Sep 2020 04:05:01

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:04:49', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'e543a863-4db2-4130-afe1-3b62f90b70b7'	System	01 Sep 2020 04:05:01
User entered 'No (N)'	System	01 Sep 2020 04:05:01

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:04:57', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'e543a863-4db2-4130-afe1-3b62f90b70b7'	System	01 Sep 2020 04:05:01
User entered '01 Sep 2020 00:04'	System	01 Sep 2020 04:05:01

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 15:10'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 2'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:10:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T22:58:29', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '4e8d2419-92ec-4224-a5d9-2b1bba90bb1b'	System	02 Sep 2020 02:59:02
User entered 'Yes (Y)'	System	02 Sep 2020 02:59:02

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:10:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T22:58:43', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '4e8d2419-92ec-4224-a5d9-2b1bba90bb1b' User entered '96.1'	System	02 Sep 2020 02:59:02

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T22:58:49', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '4e8d2419-92ec-4224-a5d9-2b1bba90bb1b'	System	02 Sep 2020 02:59:02
User entered 'No (N)'	System	02 Sep 2020 02:59:02

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:10:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T22:58:58', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '4e8d2419-92ec-4224-a5d9-2b1bba90bb1b'	System	02 Sep 2020 02:59:02
User entered '01 Sep 2020 22:58'	System	02 Sep 2020 02:59:02

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 3'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:10:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:02:47', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '79bcf885-7b57-47cd-870a-dc03346d5db4'	System	03 Sep 2020 04:03:15
User entered 'Yes (Y)'	System	03 Sep 2020 04:03:15

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:10:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:03:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '79bcf885-7b57-47cd-870a-dc03346d5db4'	System	03 Sep 2020 04:03:15
User entered '97.1'	System	03 Sep 2020 04:03:15

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:03:07', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '79bcf885-7b57-47cd-870a-dc03346d5db4'	System	03 Sep 2020 04:03:15
User entered 'No (N)'	System	03 Sep 2020 04:03:15

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:10:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:03:14', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '79bcf885-7b57-47cd-870a-dc03346d5db4'	System	03 Sep 2020 04:03:15
User entered '03 Sep 2020 00:03'	System	03 Sep 2020 04:03:15

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 4'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:10:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:38:35', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd4b6b1d6-eb36-40a6-aed8-1a4483ddd93f'	System	04 Sep 2020 03:39:03
User entered 'Yes (Y)'	System	04 Sep 2020 03:39:03

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:10:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:38:44', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd4b6b1d6-eb36-40a6-aed8-1a4483ddd93f'	System	04 Sep 2020 03:39:03
User entered '96.6'	System	04 Sep 2020 03:39:03

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:38:51', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd4b6b1d6-eb36-40a6-aed8-1a4483ddd93f'	System	04 Sep 2020 03:39:03
User entered 'No (N)'	System	04 Sep 2020 03:39:03

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:10:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:38:59', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd4b6b1d6-eb36-40a6-aed8-1a4483ddd93f'	System	04 Sep 2020 03:39:03
User entered '03 Sep 2020 23:38'	System	04 Sep 2020 03:39:03

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 5'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:10:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:55:48', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7491bc0e-daed-4849-b568-9d4c0e1f901a'	System	05 Sep 2020 02:56:20
User entered 'Yes (Y)'	System	05 Sep 2020 02:56:20

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:10:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:56:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7491bc0e-daed-4849-b568-9d4c0e1f901a' User entered '97.2'	System	05 Sep 2020 02:56:20
	System	05 Sep 2020 02:56:20

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:56:10', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7491bc0e-daed-4849-b568-9d4c0e1f901a'	System	05 Sep 2020 02:56:20
User entered 'No (N)'	System	05 Sep 2020 02:56:20

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:10:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:56:17', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7491bc0e-daed-4849-b568-9d4c0e1f901a'	System	05 Sep 2020 02:56:20
User entered '04 Sep 2020 22:56'	System	05 Sep 2020 02:56:20

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 6'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:10:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:13:30', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd95d0d83-330a-440b-9d8a-7b708c56eedd'	System	06 Sep 2020 03:14:00
User entered 'Yes (Y)'	System	06 Sep 2020 03:14:00

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:10:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:13:41', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd95d0d83-330a-440b-9d8a-7b708c56eedd'	System	06 Sep 2020 03:14:00
User entered '96.9'	System	06 Sep 2020 03:14:00

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:13:48', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd95d0d83-330a-440b-9d8a-7b708c56eedd'	System	06 Sep 2020 03:14:00
User entered 'No (N)'	System	06 Sep 2020 03:14:00

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:10:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:13:55', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd95d0d83-330a-440b-9d8a-7b708c56eedd'	System	06 Sep 2020 03:14:00
User entered '05 Sep 2020 23:13'	System	06 Sep 2020 03:14:00

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 7'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:10:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:09:42', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '2a1a7cc8-ca55-4b5a-84b3-7f2fd43bdaf6'	System	07 Sep 2020 03:10:11
User entered 'Yes (Y)'	System	07 Sep 2020 03:10:11

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:10:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:09:52', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '2a1a7cc8-ca55-4b5a-84b3-7f2fd43bdaf6'	System	07 Sep 2020 03:10:11
User entered '97.6'	System	07 Sep 2020 03:10:11

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:09:58', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '2a1a7cc8-ca55-4b5a-84b3-7f2fd43bdaf6'	System	07 Sep 2020 03:10:11
User entered 'No (N)'	System	07 Sep 2020 03:10:11

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:10:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:10:06', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '2a1a7cc8-ca55-4b5a-84b3-7f2fd43bdaf6'	System	07 Sep 2020 03:10:11
User entered '06 Sep 2020 23:10'	System	07 Sep 2020 03:10:11

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T11:58:40', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd155c3e9-ed0b-4d98-aaa6-b834d41efd6e'	System	31 Aug 2020 16:01:56
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 16:01:56

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T11:59:07', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd155c3e9-ed0b-4d98-aaa6-b834d41efd6e'	System	31 Aug 2020 16:01:56
User entered 'Yes (Y)'	System	31 Aug 2020 16:01:56

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:00:13', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd155c3e9-ed0b-4d98-aaa6-b834d41efd6e' User entered '4'	System	31 Aug 2020 16:01:56
	System	31 Aug 2020 16:01:56

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:00:21', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd155c3e9-ed0b-4d98-aaa6-b834d41efd6e'	System	31 Aug 2020 16:01:56
User entered 'No (N)'	System	31 Aug 2020 16:01:56

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:00:33', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd155c3e9-ed0b-4d98-aaa6-b834d41efd6e'	System	31 Aug 2020 16:01:56
User entered 'None (1)'	System	31 Aug 2020 16:01:56

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:00:56', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd155c3e9-ed0b-4d98-aaa6-b834d41efd6e'	System	31 Aug 2020 16:01:56
User entered '31 Aug 2020 12:00'	System	31 Aug 2020 16:01:56

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:45'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 14:15'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:01:36', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '57f3402c-e476-4bc8-b2fc-c424dec80591'	System	01 Sep 2020 04:05:45
User entered 'None (1)'	System	01 Sep 2020 04:05:45

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:01:42', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '57f3402c-e476-4bc8-b2fc-c424dec80591'	System	01 Sep 2020 04:05:45
User entered 'Yes (Y)'	System	01 Sep 2020 04:05:45

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:01:51', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '57f3402c-e476-4bc8-b2fc-c424dec80591' User entered '2'	System	01 Sep 2020 04:05:45
	System	01 Sep 2020 04:05:45

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:01:56', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '57f3402c-e476-4bc8-b2fc-c424dec80591'	System	01 Sep 2020 04:05:45
User entered 'No (N)'	System	01 Sep 2020 04:05:45

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:05:25', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '57f3402c-e476-4bc8-b2fc-c424dec80591'	System	01 Sep 2020 04:05:45
User entered 'None (1)'	System	01 Sep 2020 04:05:45

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:05:40', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '57f3402c-e476-4bc8-b2fc-c424dec80591'	System	01 Sep 2020 04:05:45
User entered '01 Sep 2020 00:05'	System	01 Sep 2020 04:05:45

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 15:10'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 2'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T22:59:15', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd6a07af6-b09d-46fc-ad61-aa47ad3e3397'	System	02 Sep 2020 02:59:56
User entered 'None (1)'	System	02 Sep 2020 02:59:56

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:10:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T22:59:25', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd6a07af6-b09d-46fc-ad61-aa47ad3e3397'	System	02 Sep 2020 02:59:56
User entered 'No (N)'	System	02 Sep 2020 02:59:56

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T22:59:32', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd6a07af6-b09d-46fc-ad61-aa47ad3e3397'	System	02 Sep 2020 02:59:56
User entered 'No (N)'	System	02 Sep 2020 02:59:56

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T22:59:42', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd6a07af6-b09d-46fc-ad61-aa47ad3e3397'	System	02 Sep 2020 02:59:56
User entered 'None (1)'	System	02 Sep 2020 02:59:56

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:10:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T22:59:54', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd6a07af6-b09d-46fc-ad61-aa47ad3e3397'	System	02 Sep 2020 02:59:56
User entered '01 Sep 2020 22:59'	System	02 Sep 2020 02:59:56

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 3'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:03:23', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd260181a-86ee-46fb-969b-b0108e05b739'	System	03 Sep 2020 04:03:50
User entered 'None (1)'	System	03 Sep 2020 04:03:50

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:10:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:03:28', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd260181a-86ee-46fb-969b-b0108e05b739'	System	03 Sep 2020 04:03:50
User entered 'No (N)'	System	03 Sep 2020 04:03:50

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:03:33', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd260181a-86ee-46fb-969b-b0108e05b739'	System	03 Sep 2020 04:03:50
User entered 'No (N)'	System	03 Sep 2020 04:03:50

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:03:39', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd260181a-86ee-46fb-969b-b0108e05b739'	System	03 Sep 2020 04:03:50
User entered 'None (1)'	System	03 Sep 2020 04:03:50

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:10:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:03:49', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd260181a-86ee-46fb-969b-b0108e05b739'	System	03 Sep 2020 04:03:50
User entered '03 Sep 2020 00:03'	System	03 Sep 2020 04:03:50

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 4'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:39:08', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'a9e15647-d581-49c1-bf56-fcbea2609b61'	System	04 Sep 2020 03:39:41
User entered 'None (1)'	System	04 Sep 2020 03:39:41

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:10:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:39:15', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'a9e15647-d581-49c1-bf56-fcbea2609b61'	System	04 Sep 2020 03:39:41
User entered 'No (N)'	System	04 Sep 2020 03:39:41

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:39:20', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'a9e15647-d581-49c1-bf56-fcbea2609b61'	System	04 Sep 2020 03:39:41
User entered 'No (N)'	System	04 Sep 2020 03:39:41

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:39:27', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'a9e15647-d581-49c1-bf56-fcbea2609b61'	System	04 Sep 2020 03:39:41
User entered 'None (1)'	System	04 Sep 2020 03:39:41

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:10:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:39:37', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'a9e15647-d581-49c1-bf56-fcbea2609b61'	System	04 Sep 2020 03:39:41
User entered '03 Sep 2020 23:39'	System	04 Sep 2020 03:39:41

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 5'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:56:28', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '47ae921c-a9d6-4b63-8766-c69790682a31'	System	05 Sep 2020 02:56:53
User entered 'None (1)'	System	05 Sep 2020 02:56:53

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:10:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:56:34', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '47ae921c-a9d6-4b63-8766-c69790682a31'	System	05 Sep 2020 02:56:53
User entered 'No (N)'	System	05 Sep 2020 02:56:53

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:56:38', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '47ae921c-a9d6-4b63-8766-c69790682a31'	System	05 Sep 2020 02:56:53
User entered 'No (N)'	System	05 Sep 2020 02:56:53

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:56:43', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '47ae921c-a9d6-4b63-8766-c69790682a31'	System	05 Sep 2020 02:56:53
User entered 'None (1)'	System	05 Sep 2020 02:56:53

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:10:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:56:50', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '47ae921c-a9d6-4b63-8766-c69790682a31'	System	05 Sep 2020 02:56:53
User entered '04 Sep 2020 22:56'	System	05 Sep 2020 02:56:53

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 6'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:03', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd2d3e504-e524-425b-b25c-df30b33fa5ff'	System	06 Sep 2020 03:14:31
User entered 'None (1)'	System	06 Sep 2020 03:14:31

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:10:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:09', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd2d3e504-e524-425b-b25c-df30b33fa5ff'	System	06 Sep 2020 03:14:31
User entered 'No (N)'	System	06 Sep 2020 03:14:31

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:14', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd2d3e504-e524-425b-b25c-df30b33fa5ff'	System	06 Sep 2020 03:14:31
User entered 'No (N)'	System	06 Sep 2020 03:14:31

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:20', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd2d3e504-e524-425b-b25c-df30b33fa5ff'	System	06 Sep 2020 03:14:31
User entered 'None (1)'	System	06 Sep 2020 03:14:31

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:10:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:28', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd2d3e504-e524-425b-b25c-df30b33fa5ff'	System	06 Sep 2020 03:14:31
User entered '05 Sep 2020 23:14'	System	06 Sep 2020 03:14:31

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 7'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:10:14', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'b3590ff1-deb3-48f3-b558-da9ed67856fd'	System	07 Sep 2020 03:10:47
User entered 'None (1)'	System	07 Sep 2020 03:10:47

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:10:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:10:20', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'b3590ff1-deb3-48f3-b558-da9ed67856fd'	System	07 Sep 2020 03:10:47
User entered 'No (N)'	System	07 Sep 2020 03:10:47

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:10:25', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'b3590ff1-deb3-48f3-b558-da9ed67856fd'	System	07 Sep 2020 03:10:47
User entered 'No (N)'	System	07 Sep 2020 03:10:47

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:10:33', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'b3590ff1-deb3-48f3-b558-da9ed67856fd'	System	07 Sep 2020 03:10:47
User entered 'None (1)'	System	07 Sep 2020 03:10:47

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:10:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:10:44', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'b3590ff1-deb3-48f3-b558-da9ed67856fd'	System	07 Sep 2020 03:10:47
User entered '06 Sep 2020 23:10'	System	07 Sep 2020 03:10:47

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:01:16', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9473c0fa-778d-42e1-9ea5-ce4d87527767'	System	31 Aug 2020 16:03:16
User entered 'None (0)'	System	31 Aug 2020 16:03:16

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:01:22', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9473c0fa-778d-42e1-9ea5-ce4d87527767'	System	31 Aug 2020 16:03:16
User entered 'None (0)'	System	31 Aug 2020 16:03:16

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:01:27', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9473c0fa-778d-42e1-9ea5-ce4d87527767'	System	31 Aug 2020 16:03:16
User entered 'None (0)'	System	31 Aug 2020 16:03:16

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:01:34', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9473c0fa-778d-42e1-9ea5-ce4d87527767'	System	31 Aug 2020 16:03:16
User entered 'None (0)'	System	31 Aug 2020 16:03:16

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:01:41', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9473c0fa-778d-42e1-9ea5-ce4d87527767'	System	31 Aug 2020 16:03:16
User entered 'None (0)'	System	31 Aug 2020 16:03:16

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:01:46', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9473c0fa-778d-42e1-9ea5-ce4d87527767'	System	31 Aug 2020 16:03:16
User entered 'None (0)'	System	31 Aug 2020 16:03:16

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:01:53', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9473c0fa-778d-42e1-9ea5-ce4d87527767'	System	31 Aug 2020 16:03:16
User entered 'No (N)'	System	31 Aug 2020 16:03:16

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:02:03', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9473c0fa-778d-42e1-9ea5-ce4d87527767'	System	31 Aug 2020 16:03:16
User entered '31 Aug 2020 12:02'	System	31 Aug 2020 16:03:16

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:45'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 14:15'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:02:47', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c701adb8-3e56-4711-8a9e-981584f046eb'	System	01 Sep 2020 04:04:06
User entered 'None (0)'	System	01 Sep 2020 04:04:06

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:03:01', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c701adb8-3e56-4711-8a9e-981584f046eb'	System	01 Sep 2020 04:04:06
User entered 'None (0)'	System	01 Sep 2020 04:04:06

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:03:05', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c701adb8-3e56-4711-8a9e-981584f046eb'	System	01 Sep 2020 04:04:06
User entered 'None (0)'	System	01 Sep 2020 04:04:06

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:03:10', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c701adb8-3e56-4711-8a9e-981584f046eb'	System	01 Sep 2020 04:04:06
User entered 'None (0)'	System	01 Sep 2020 04:04:06

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:03:18', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c701adb8-3e56-4711-8a9e-981584f046eb'	System	01 Sep 2020 04:04:06
User entered 'None (0)'	System	01 Sep 2020 04:04:06

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:03:29', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c701adb8-3e56-4711-8a9e-981584f046eb'	System	01 Sep 2020 04:04:06
User entered 'None (0)'	System	01 Sep 2020 04:04:06

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:03:36', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c701adb8-3e56-4711-8a9e-981584f046eb'	System	01 Sep 2020 04:04:06
User entered 'No (N)'	System	01 Sep 2020 04:04:06

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:04:03', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c701adb8-3e56-4711-8a9e-981584f046eb'	System	01 Sep 2020 04:04:06
User entered '01 Sep 2020 00:04'	System	01 Sep 2020 04:04:06

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 15:10'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 2'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:47

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T23:00:08', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cbaf3108-f0a7-4042-b358-c69941cef53b'	System	02 Sep 2020 03:01:11
User entered 'None (0)'	System	02 Sep 2020 03:01:11

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:47

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T23:00:12', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cbaf3108-f0a7-4042-b358-c69941cef53b'	System	02 Sep 2020 03:01:11
User entered 'None (0)'	System	02 Sep 2020 03:01:11

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T23:00:17', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cbaf3108-f0a7-4042-b358-c69941cef53b'	System	02 Sep 2020 03:01:11
User entered 'None (0)'	System	02 Sep 2020 03:01:11

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T23:00:21', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cbaf3108-f0a7-4042-b358-c69941cef53b'	System	02 Sep 2020 03:01:11
User entered 'None (0)'	System	02 Sep 2020 03:01:11

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T23:00:34', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cbaf3108-f0a7-4042-b358-c69941cef53b'	System	02 Sep 2020 03:01:11
User entered 'None (0)'	System	02 Sep 2020 03:01:11

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:47

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T23:00:41', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cbaf3108-f0a7-4042-b358-c69941cef53b'	System	02 Sep 2020 03:01:11
User entered 'None (0)'	System	02 Sep 2020 03:01:11

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T23:00:50', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cbaf3108-f0a7-4042-b358-c69941cef53b'	System	02 Sep 2020 03:01:11
User entered 'No (N)'	System	02 Sep 2020 03:01:11

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:47

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T23:01:06', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cbaf3108-f0a7-4042-b358-c69941cef53b'	System	02 Sep 2020 03:01:11
User entered '01 Sep 2020 23:01'	System	02 Sep 2020 03:01:11

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 3'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:47

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:03:55', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c340e86c-f272-4340-9c66-49360aada8b2'	System	03 Sep 2020 04:04:54
User entered 'None (0)'	System	03 Sep 2020 04:04:54

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:47

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c340e86c-f272-4340-9c66-49360aada8b2'	System	03 Sep 2020 04:04:54
User entered 'None (0)'	System	03 Sep 2020 04:04:54

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:04:03', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c340e86c-f272-4340-9c66-49360aada8b2'	System	03 Sep 2020 04:04:54
User entered 'None (0)'	System	03 Sep 2020 04:04:54

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:04:09', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c340e86c-f272-4340-9c66-49360aada8b2'	System	03 Sep 2020 04:04:54
User entered 'None (0)'	System	03 Sep 2020 04:04:54

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:04:14', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c340e86c-f272-4340-9c66-49360aada8b2'	System	03 Sep 2020 04:04:54
User entered 'None (0)'	System	03 Sep 2020 04:04:54

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:47

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:04:18', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c340e86c-f272-4340-9c66-49360aada8b2'	System	03 Sep 2020 04:04:54
User entered 'None (0)'	System	03 Sep 2020 04:04:54

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:04:36', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c340e86c-f272-4340-9c66-49360aada8b2'	System	03 Sep 2020 04:04:54
User entered 'No (N)'	System	03 Sep 2020 04:04:54

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:47

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:04:49', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c340e86c-f272-4340-9c66-49360aada8b2'	System	03 Sep 2020 04:04:54
User entered '03 Sep 2020 00:04'	System	03 Sep 2020 04:04:54

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 4'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:47

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:39:46', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7a8c59c6-c9ce-46bd-9520-045971ddda35'	System	04 Sep 2020 03:40:33
User entered 'None (0)'	System	04 Sep 2020 03:40:33

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:47

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:39:51', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7a8c59c6-c9ce-46bd-9520-045971ddda35'	System	04 Sep 2020 03:40:33
User entered 'None (0)'	System	04 Sep 2020 03:40:33

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:39:55', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7a8c59c6-c9ce-46bd-9520-045971ddda35'	System	04 Sep 2020 03:40:33
User entered 'None (0)'	System	04 Sep 2020 03:40:33

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:40:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7a8c59c6-c9ce-46bd-9520-045971ddda35'	System	04 Sep 2020 03:40:33
User entered 'None (0)'	System	04 Sep 2020 03:40:33

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:40:05', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7a8c59c6-c9ce-46bd-9520-045971ddda35'	System	04 Sep 2020 03:40:33
User entered 'None (0)'	System	04 Sep 2020 03:40:33

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:47

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:40:08', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7a8c59c6-c9ce-46bd-9520-045971ddda35'	System	04 Sep 2020 03:40:33
User entered 'None (0)'	System	04 Sep 2020 03:40:33

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:40:21', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7a8c59c6-c9ce-46bd-9520-045971ddda35'	System	04 Sep 2020 03:40:33
User entered 'No (N)'	System	04 Sep 2020 03:40:33

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:47

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:40:32', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7a8c59c6-c9ce-46bd-9520-045971ddda35'	System	04 Sep 2020 03:40:33
User entered '03 Sep 2020 23:40'	System	04 Sep 2020 03:40:33

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 5'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:47

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:56:58', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'db708bcf-2d3e-44d8-a7f2-963ac7ac9043'	System	05 Sep 2020 02:57:52
User entered 'None (0)'	System	05 Sep 2020 02:57:52

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:47

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:57:02', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'db708bcf-2d3e-44d8-a7f2-963ac7ac9043'	System	05 Sep 2020 02:57:52
User entered 'None (0)'	System	05 Sep 2020 02:57:52

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:57:06', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'db708bcf-2d3e-44d8-a7f2-963ac7ac9043'	System	05 Sep 2020 02:57:52
User entered 'None (0)'	System	05 Sep 2020 02:57:52

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:57:10', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'db708bcf-2d3e-44d8-a7f2-963ac7ac9043'	System	05 Sep 2020 02:57:52
User entered 'None (0)'	System	05 Sep 2020 02:57:52

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:57:15', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'db708bcf-2d3e-44d8-a7f2-963ac7ac9043'	System	05 Sep 2020 02:57:52
User entered 'None (0)'	System	05 Sep 2020 02:57:52

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:47

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:57:21', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'db708bcf-2d3e-44d8-a7f2-963ac7ac9043'	System	05 Sep 2020 02:57:52
User entered 'None (0)'	System	05 Sep 2020 02:57:52

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:57:36', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'db708bcf-2d3e-44d8-a7f2-963ac7ac9043'	System	05 Sep 2020 02:57:52
User entered 'No (N)'	System	05 Sep 2020 02:57:52

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:47

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:57:49', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'db708bcf-2d3e-44d8-a7f2-963ac7ac9043'	System	05 Sep 2020 02:57:52
User entered '04 Sep 2020 22:57'	System	05 Sep 2020 02:57:52

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 6'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:47

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:36', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '8026e0ff-982c-4418-a441-45a538a2afcd'	System	06 Sep 2020 03:15:16
User entered 'None (0)'	System	06 Sep 2020 03:15:16

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:47

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:40', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '8026e0ff-982c-4418-a441-45a538a2afcd'	System	06 Sep 2020 03:15:16
User entered 'None (0)'	System	06 Sep 2020 03:15:16

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:44', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '8026e0ff-982c-4418-a441-45a538a2afcd'	System	06 Sep 2020 03:15:16
User entered 'None (0)'	System	06 Sep 2020 03:15:16

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:48', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '8026e0ff-982c-4418-a441-45a538a2afcd'	System	06 Sep 2020 03:15:16
User entered 'None (0)'	System	06 Sep 2020 03:15:16

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:52', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '8026e0ff-982c-4418-a441-45a538a2afcd'	System	06 Sep 2020 03:15:16
User entered 'None (0)'	System	06 Sep 2020 03:15:16

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:47

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:56', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '8026e0ff-982c-4418-a441-45a538a2afcd'	System	06 Sep 2020 03:15:16
User entered 'None (0)'	System	06 Sep 2020 03:15:16

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:15:02', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '8026e0ff-982c-4418-a441-45a538a2afcd'	System	06 Sep 2020 03:15:16
User entered 'No (N)'	System	06 Sep 2020 03:15:16

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:47

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:15:15', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '8026e0ff-982c-4418-a441-45a538a2afcd'	System	06 Sep 2020 03:15:16
User entered '05 Sep 2020 23:15'	System	06 Sep 2020 03:15:16

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 7'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:47

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:10:52', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9134aa1e-9351-4652-842d-28f2df59b75a'	System	07 Sep 2020 03:11:32
User entered 'None (0)'	System	07 Sep 2020 03:11:32

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:47

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:10:55', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9134aa1e-9351-4652-842d-28f2df59b75a'	System	07 Sep 2020 03:11:32
User entered 'None (0)'	System	07 Sep 2020 03:11:32

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:11:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9134aa1e-9351-4652-842d-28f2df59b75a'	System	07 Sep 2020 03:11:32
User entered 'None (0)'	System	07 Sep 2020 03:11:32

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:11:04', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9134aa1e-9351-4652-842d-28f2df59b75a'	System	07 Sep 2020 03:11:32
User entered 'None (0)'	System	07 Sep 2020 03:11:32

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:11:08', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9134aa1e-9351-4652-842d-28f2df59b75a'	System	07 Sep 2020 03:11:32
User entered 'None (0)'	System	07 Sep 2020 03:11:32

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:47

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:11:12', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9134aa1e-9351-4652-842d-28f2df59b75a'	System	07 Sep 2020 03:11:32
User entered 'None (0)'	System	07 Sep 2020 03:11:32

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:11:20', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9134aa1e-9351-4652-842d-28f2df59b75a'	System	07 Sep 2020 03:11:32
User entered 'No (N)'	System	07 Sep 2020 03:11:32

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:47

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:11:29', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9134aa1e-9351-4652-842d-28f2df59b75a'	System	07 Sep 2020 03:11:32
User entered '06 Sep 2020 23:11'	System	07 Sep 2020 03:11:32

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:10:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:56:29

US3672278

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:44:21
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 04:52:46
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'added pd due to subject being oow ' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 18:57:06
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	11 Sep 2020 18:56:29
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:56:29

US3672278

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:44:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Sep 2020 18:56:29

US3672278

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:44:21
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:56:29

US3672278

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:44:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:57:25

US3672278

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 18:57:25

US3672278

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 19:29:25

US3672278

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 19:29:25

US3672278

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Sep 2020 19:29:25

US3672278

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 19:29:25

US3672278

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 19:29:29

US3672278

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 19:29:29

US3672278

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 20:12:54

US3672278

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 20:12:54

US3672278

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Sep 2020 20:12:54

US3672278

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:12:54

US3672278

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 20:13:01

US3672278

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 20:13:01

US3672278

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 20:19:01

US3672278

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 20:19:01

US3672278

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Sep 2020 20:19:01

US3672278

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	28 Sep 2020 20:19:01

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '10:16'	(b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '28 Sep 2020 10:16'	System	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	(b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '77'	(b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '105'	(b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '68'	(b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:10:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:10:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 20:19:53

US3672278

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 20:19:53

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:20:21

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

[If No, reason not given](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please complete 'Dosing Discontinuation' page. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 04:58:58
Query 'Per CDM: Please complete 'Dosing Discontinuation' page. Thank you.' answered with 'CRF COMPLETED' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 23:14:37
User opened query 'Per CDM: Please complete 'Dosing Discontinuation' page. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 05:32:04
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4), (b) (6)	28 Sep 2020 20:20:21

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:20:21

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 20:20:21

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:20:21

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:20:21

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 20:20:21

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:20:21

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 20:20:21

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 20:20:21

US3672278

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 20:20:35

US3672278

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 20:20:35

US3672278

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:47

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:43'	(b) (4), (b) (6)	28 Sep 2020 20:20:35

US3672278

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '28 Sep 2020 10:43'	System	28 Sep 2020 20:20:35

US3672278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:10:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 20:20:51

US3672278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:10:47

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	28 Sep 2020 20:20:51

US3672278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:10:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 20:20:51

US3672278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:10:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:30'	(b) (4), (b) (6)	28 Sep 2020 20:20:51

US3672278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '28 Sep 2020 10:30'	System	28 Sep 2020 20:20:51

US3672278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:10:47

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	28 Sep 2020 20:20:51

US3672278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:10:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:20:51

US3672278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:10:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:20:51

US3672278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 20:20:51

US3672278

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 20:20:57

US3672278

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 20:20:57

US3672278

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 23:25:21

US3672278

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 23:25:21

US3672278

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Oct 2020 23:25:21

US3672278

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:25:21

US3672278

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 23:25:25

US3672278

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 23:25:25

US3672278

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 23:25:35

US3672278

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 23:25:35

US3672278

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Oct 2020 23:25:35

US3672278

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:25:35

US3672278

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 23:25:38

US3672278

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 23:25:38

US3672278

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 20:30:26

US3672278

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 20:30:26

US3672278

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Oct 2020 20:30:26

US3672278

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:30:26

US3672278

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 20:30:29

US3672278

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:30:29

US3672278

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 15:59:09

US3672278

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 15:59:09

US3672278

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Oct 2020 15:59:09

US3672278

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:10:47

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	23 Oct 2020 15:59:09

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '10:07'	(b) (4), (b) (6)	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '23 Oct 2020 10:07'	System	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	(b) (4), (b) (6)	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '79'	(b) (4), (b) (6)	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '17'	(b) (4), (b) (6)	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '97'	(b) (4), (b) (6)	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 19:07:21
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 16:00:06
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		23 Oct 2020 15:59:52
User entered '54'	(b) (4), (b) (6)	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:10:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 16:00:40

US3672278

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:10:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 16:00:40

US3672278

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 16:01:06

US3672278

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 16:01:06

US3672278

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:15'	(b) (4), (b) (6)	23 Oct 2020 16:01:06

US3672278

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered '23 Oct 2020 10:15'	System	23 Oct 2020 16:01:06

US3672278

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 16:01:13

US3672278

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:01:13

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 64'	System	31 Aug 2020 15:45:08

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-10-31T19:03:22', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'a429dd47-49cf-4bad-b6bd-40c908666a78' User entered 'No (N)'	System	31 Oct 2020 23:04:05
	System	31 Oct 2020 23:04:05

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-10-31T19:03:33', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'a429dd47-49cf-4bad-b6bd-40c908666a78'	System	31 Oct 2020 23:04:05
User entered 'No (N)'	System	31 Oct 2020 23:04:05

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-10-31T19:04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'a429dd47-49cf-4bad-b6bd-40c908666a78' User entered '31 Oct 2020 19:04:00'	System	31 Oct 2020 23:04:05
	System	31 Oct 2020 23:04:05

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 15:45:08

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 71'	System	31 Aug 2020 15:45:08

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-11-07T18:09:12', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'fbfb68c4-10b3-4f77-9809-940c5ba96723'	System	07 Nov 2020 23:09:57
User entered 'No (N)'	System	07 Nov 2020 23:09:57

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-11-07T18:09:20', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'fbfb68c4-10b3-4f77-9809-940c5ba96723'	System	07 Nov 2020 23:09:57
User entered 'No (N)'	System	07 Nov 2020 23:09:57

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-11-07T18:09:54', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'fbfb68c4-10b3-4f77-9809-940c5ba96723' User entered '07 Nov 2020 18:09:54'	System	07 Nov 2020 23:09:57
	System	07 Nov 2020 23:09:57

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 15:45:08

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 78'	System	31 Aug 2020 15:45:08

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-11-14T23:29:10', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '53b57dd9-24f5-41d4-b9f1-13609f33e8c2'	System	15 Nov 2020 04:30:02
User entered 'No (N)'	System	15 Nov 2020 04:30:02

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-11-14T23:29:25', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '53b57dd9-24f5-41d4-b9f1-13609f33e8c2'	System	15 Nov 2020 04:30:02
User entered 'Yes (Y)'	System	15 Nov 2020 04:30:02

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-11-14T23:29:38', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '53b57dd9-24f5-41d4-b9f1-13609f33e8c2'	System	15 Nov 2020 04:30:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Nov 2020 04:30:02

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-11-14T23:29:50', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '53b57dd9-24f5-41d4-b9f1-13609f33e8c2'	System	15 Nov 2020 04:30:02
User entered '14 Nov 2020 23:29:50'	System	15 Nov 2020 04:30:02

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 15:45:08

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:45:08
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 01:53:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '28 Oct 2020 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '01 Nov 2020 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '04 Nov 2020 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '08 Nov 2020 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '11 Nov 2020 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '15 Nov 2020 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:53:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:53:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:53:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:53:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:53:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:53:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:53:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 01:53:12

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:10:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 21:44:17

US3672278

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 21:44:17

US3672278

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Nov 2020 21:44:17

US3672278

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:10:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 21:44:17

US3672278

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 21:44:32

US3672278

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:10:47

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 21:44:32

US3672278

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:10:47

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:59:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:57:30

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 13:05:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:01
User entered 'USA-US116-2020-mRNA-1273-P301000001'	System	12 Sep 2020 19:18:32
User entered 'New'	(b) (4), (b) (6)	12 Sep 2020 19:18:32

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'PV Query:: Please specify type of stroke the subject experienced (i.e. ischemic, hemorrhagic)' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:29:03
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Ischaemic stroke, LLT: Ischemic stroke - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 23:03:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 23:03:22
Query 'PV Query:: Please specify type of stroke the subject experienced (i.e. ischemic, hemorrhagic)' answered with 'type of stroke updated' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:48:40
Data point term sent to Coder	System	22 Oct 2020 16:48:26
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 16:48:23
Coding entries removed.	(b) (4), (b) (6)	22 Oct 2020 16:48:23
User entered 'ischemic STROKE (frontal lobe)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:48:23
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 13:05:42
User opened query 'PV Query:: Please specify type of stroke the subject experienced (i.e. ischemic, hemorrhagic)' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:55:25
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 11:20:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 11:20:39
Data point term sent to Coder	System	11 Sep 2020 19:00:33
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 19:00:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 19:00:04

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Frontal Lobe Stroke' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 19:00:04
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 18:59:22
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:59:22

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 13:05:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 13:05:44
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 13:05:46
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 13:05:49
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	11 Sep 2020 19:00:29
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Sep 2020 19:00:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 19:00:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Sep 2020 18:59:22
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	11 Sep 2020 18:59:22
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	11 Sep 2020 18:59:22

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 19:00:29
User entered '10 Sep 2020 UN:UN' (non-conformant).	System	11 Sep 2020 18:59:22

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:23:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 21:04:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:23:26
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 21:04:52
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:59:22

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:23:28
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:59:22

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6)	16 Sep 2020 19:54:44
	System	11 Sep 2020 18:59:22

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

Severity

Audit	User	Time (GMT)
Query 'PV Query: Please confirm intensity of grade 3 as events resulted in hospitalization, and consider upgrading to grade 4.' answered with 'Severity recorded as Grade 3 in error, correction made.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 20:08:47
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:08:47
User opened query 'PV Query: Please confirm intensity of grade 3 as events resulted in hospitalization, and consider upgrading to grade 4.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:37:53
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:25:49
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 19:09:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 19:09:29
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 19:09:29
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 18:59:22
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:59:22

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:26:50
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 19:00:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 19:00:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 19:00:04
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 18:59:22
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:59:22

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:29:17
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'last covid test was completed in office and subject results were negative' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:49:11
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:54:59
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		11 Sep 2020 19:00:04
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		11 Sep 2020 19:00:04
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 19:00:04
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	11 Sep 2020 18:59:22
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'Per CDM: The reason provided for study treatment not given on Exposure (V2D29) page is 'Physician withheld dose due to Adverse Event' however, 'none' is recorded here. Please confirm the 'Action taken with investigational product' again and update it appropriately or else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:35:27
Query 'Per CDM: The reason provided for study treatment not given on Exposure (V2D29) page is 'Physician withheld dose due to Adverse Event' however, 'none' is recorded here. Please confirm the 'Action taken with investigational product' again and update it appropriately or else clarify. Thank you ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 20:01:16
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 20:01:11
User opened query 'Per CDM: The reason provided for study treatment not given on Exposure (V2D29) page is 'Physician withheld dose due to Adverse Event' however, 'none' is recorded here. Please confirm the 'Action taken with investigational product' again and update it appropriately or else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 05:31:01
User entered 'None (NONE)'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe (i.e., PLAVIX per SAE Narrative). Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 23:57:40
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe (i.e., PLAVIX per SAE Narrative). Please review and add a Con Medication as appropriate or update action taken.' answered with 'all conmeds related to event listed' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:51:56
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe (i.e., PLAVIX per SAE Narrative). Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:34:39
User entered '1'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 17:13:57
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'RESOLVED WITH SEQUELAIE- AE of speech deficit.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 21:05:02
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 21:04:52
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 16:54:37
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:29:25
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'still resolving' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:51:45
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:54:32
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	30 Oct 2020 21:05:16
User entered 'AE of speech deficit' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 21:05:16
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	30 Oct 2020 21:04:52
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'Per DM CLR Re-query: Response noted However, ONGOING SPEECH DEFICIT AE has not been added in AE eCRF. Please review and confirm if this should be recorded as a separate entry in the AE eCRF. If 'Yes' update accordingly or clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 05:56:54
Query 'Per DM CLR Re-query: Response noted However, ONGOING SPEECH DEFICIT AE has not been added in AE eCRF. Please review and confirm if this should be recorded as a separate entry in the AE eCRF. If 'Yes' update accordingly or clarify.' answered with 'ongoing speech deficit added to adverse events' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:50:01
User opened query 'Per DM CLR Re-query: Response noted However, ONGOING SPEECH DEFICIT AE has not been added in AE eCRF. Please review and confirm if this should be recorded as a separate entry in the AE eCRF. If 'Yes' update accordingly or clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 17:44:43
User closed query 'Per DM CLR: SAE NARRATIVE: ONGOING SPEECH DEFICIT. Please review and confirm if this should be recorded as a separate entry in the AE eCRF. If yes, please update AE eCRF. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 17:44:43
User closed query 'Per DM CLR: SAE NARRATIVE: Patient had MH of CVD, Plavix was started and will be starting speech therapy. Please review and ensure that these information were recorded in the appropriate eCRFs.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 17:38:41
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e.head CT/MRI, carotid ultrasound, etc). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 15:03:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e.head CT/MRI, carotid ultrasound, etc). Please include units and reference ranges if applicable.' answered with 'ADDED RELEVANT LAB AND DIAGNOSTIC TEST RESULTS. PLEASE LET US KNOW IF MORE INFORMATION IS NECESSARY AND WE CAN REQUEST IT.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 20:18:49
User entered 'SUBJECT IS A 78 YEAR OLD MAKE WITH HISTORY OF CVD, CAD, CHF, AND DM. DAY 8 PHONE CALL WAS MADE ON 9/11/2020 AND WAS MOSTLY COMPLETED WITH SUBJECT'S WIFE. SUBJECT'S WIFE REPORTS ON 9/10/2020. SUBJECT DEVELOPED INABILITY TO SPEAK. HE WAS ADMITTED TO THE HOSPITAL AND DIAGNOSED WITH FRONTAL LOBE STROKE. SUBJECT WAS DISCHARGED 9/11/2020 WITH ONGOING SPEECH DEFICIT. HE WAS STARTED ON PLAVIX AND WILL BE STARTING SPEECH THERAPY. MEDICAL RECORDS WERE RECEIVED WHICH INCLUDED LAB RESULTS AND DIAGNOSTIC TEST RESULTS. RELEVANT OR ABNORMAL LAB TESTS INCLUDE: PTT 28.7 SEC, PT 13.4 SEC, INR 1.0, HGA1C 7.7%. FINDINGS FROM NONCONTRAST BRAIN CT SCAN ON 09/10/20 @ 1538 INLCUDE SMALL EVOLVING ACUTE INFARCTIONS IN THE LEFT INSULAR CORTEX AND ANTERIOR LEFT CORONA RADIATA, AND NO HEMORRHAGE. ULTRASOUND CAROTID DUPLEX BILATERAL COMPLETED ON 09/10/20 @ 1840 SHOWED NO STENOSIS BILATERALLY.' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 20:18:17
Query 'Per DM CLR: SAE NARRATIVE: ONGOING SPEECH DEFICIT. Please review and confirm if this should be recorded as a separate entry in the AE eCRF. If yes, please update AE eCRF. Otherwise, clarify.' answered with 'added' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 20:00:56

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE NARRATIVE: Patient had MH of CVD, Plavix was started and will be starting speech therapy. Please review and ensure that these information were recorded in the appropriate eCRFs.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 20:00:51
User opened query 'Per DM CLR: SAE NARRATIVE: ONGOING SPEECH DEFICIT. Please review and confirm if this should be recorded as a separate entry in the AE eCRF. If yes, please update AE eCRF. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:35:11
User opened query 'Per DM CLR: SAE NARRATIVE: Patient had MH of CVD, Plavix was started and will be starting speech therapy. Please review and ensure that these information were recorded in the appropriate eCRFs.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:34:51
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e.head CT/MRI, carotid ultrasound, etc). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:55:08
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Sep 2020 19:04:35
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	11 Sep 2020 19:04:35
User entered 'Subject is a 78 year old make with history of CVD, CAD, CHF, and DM. Day 8 Phone call was made on 9/11/2020 and was mostly completed with subject's wife. Subject's wife reports on 9/10/2020. Subject developed inability to speak. He was admitted to the hospital and diagnosed with frontal lobe stroke. Subject was discharged 9/11/2020 with ongoing speech deficit. He was started on plavix and will be starting speech therapy. Medical Records will be requested.' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 19:04:35
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Sep 2020 19:00:04

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:00:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:10:47

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:15:42
User entered 'USA-US116-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	02 Nov 2020 17:15:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Speech and language abnormalities, PT: Speech disorder, LLT: Speech disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 22:33:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 22:33:04
Data point term sent to Coder	System	30 Oct 2020 21:06:21
Coding entries removed.	(b) (4), (b) (6)	30 Oct 2020 21:05:59
User entered 'SPEECH DEFICIT' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 21:05:59
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Speech and language abnormalities, PT: Speech disorder, LLT: Speech disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:59:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:59:56
Data point term sent to Coder	System	30 Oct 2020 16:46:32
User entered 'Ongoing speech deficit'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '10 Sep 2020'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave this query open until information is available.' answered with 'Speech deficit still ongoing. Should site add Speech deficit to medical history considering it is now a chronic condition?' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:10:02
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave this query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:36:38
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:39:25
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'confirm ongoing' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 21:01:20
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 13:42:26
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	30 Oct 2020 16:46:55
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	30 Oct 2020 16:45:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		30 Oct 2020 16:47:10
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		30 Oct 2020 16:47:10
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:47:10
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	30 Oct 2020 16:46:55
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:46:55
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:46:55
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:46:55
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:46:55
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:48:01
User entered 'None (NONE)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '1'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Subject's speech is still currently affected' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:10:48
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 20:10:22
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:10:22
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:36:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:18:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 18:03:18
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:39:35
Query 'Data is required. Please complete.' answered with 'see previous query' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 21:01:04
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 21:00:55
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 21:00:41
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 21:00:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 21:00:41

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 13:42:44
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Oct 2020 16:48:01
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	30 Oct 2020 16:48:01
User entered 'SUBJECT IS A 78 YEAR OLD MAKE WITH HISTORY OF CVD, CAD, CHF, AND DM. DAY 8 PHONE CALL WAS MADE ON 9/11/2020 AND WAS MOSTLY COMPLETED WITH SUBJECT'S WIFE. SUBJECT'S WIFE REPORTS ON 9/10/2020. SUBJECT DEVELOPED INABILITY TO SPEAK. HE WAS ADMITTED TO THE HOSPITAL AND DIAGNOSED WITH FRONTAL LOBE STROKE. SUBJECT WAS DISCHARGED 9/11/2020 WITH ONGOING SPEECH DEFICIT. HE WAS STARTED ON PLAVIX AND WILL BE STARTING SPEECH THERAPY. MEDICAL RECORDS WERE RECEIVED WHICH INCLUDED LAB RESULTS AND DIAGNOSTIC TEST RESULTS. RELEVANT OR ABNORMAL LAB TESTS INCLUDE: PTT 28.7 SEC, PT 13.4 SEC, INR 1.0, HGA1C 7.7%. FINDINGS FROM NONCONTRAST BRAIN CT SCAN ON 09/10/20 @ 1538 INLCUDE SMALL EVOLVING ACUTE INFARCTIONS IN THE LEFT INSULAR CORTEX AND ANTERIOR LEFT CORONA RADIATA, AND NO HEMORRHAGE. ULTRASOUND CAROTID DUPLEX BILATERAL COMPLETED ON 09/10/20 @ 1840 SHOWED NO STENOSIS BILATERALLY.' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:48:01
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Oct 2020 16:45:45
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:10:47

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 16:46:55

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:10:47

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Query 'Please update con med page to reflect all of the conmeds listed in the source. Thanks! ' canceled (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 13:45:56
User opened query 'Please update con med page to reflect all of the conmeds listed in the source. Thanks! ' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 12:57:15
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:55:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:30:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
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)	01 Sep 2020 18:39:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:39:51
Data point term sent to Coder	System	01 Sep 2020 18:39:14
User entered 'METOPROLOL'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'MYOCARDIAL INFARCTION'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered '25'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'UN UNK 1989'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:42:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:42:55
Data point term sent to Coder	System	01 Sep 2020 18:41:20
User entered 'LORATADINE'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'ALLERGIC RHINITIS'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered '10'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'UN UNK 2000'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 20:25:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 20:25:44
Data point term sent to Coder	System	28 Sep 2020 20:24:22
User entered 'aspirin'	(b) (4), (b) (6)	28 Sep 2020 20:23:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 17:38:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 17:38:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:23:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'myocardial infarction'	(b) (4), (b) (6)	28 Sep 2020 20:23:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '81'	(b) (4), (b) (6)	28 Sep 2020 20:23:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 20:23:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:23:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 20:23:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:23:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 20:23:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:23:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'un UNK 2000'	(b) (4), (b) (6)	28 Sep 2020 20:23:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 20:23:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:51
User closed query 'Per source, this was discontinued. The end date is 11Sep2020. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:51:49
Query 'Per source, this was discontinued. The end date is 11Sep2020. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:36:49
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 17:36:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 17:36:44
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User opened query 'Per source, this was discontinued. The end date is 11Sep2020. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 16:41:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 20:23:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:54
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 17:36:44
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 17:36:44
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:23:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:23:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 20:23:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 20:23:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 20:23:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 12:36:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 12:36:34
Data point term sent to Coder	System	22 Oct 2020 16:51:28
Coding entries removed.	(b) (4), (b) (6)	22 Oct 2020 16:50:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 06:13:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 06:13:54
Data point term sent to Coder	System	28 Sep 2020 20:25:23
User entered 'benadryl'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User closed query 'Per DM CLR: Please review if the specific affected location of leg cramps can be provided (e.g. Right, Left, bilateral). Review and update Indication as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:39:39
Query 'Per DM CLR: Please review if the specific affected location of leg cramps can be provided (e.g. Right, Left, bilateral). Review and update Indication as appropriate.' answered with 'location updated' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:51:03
User entered 'LEG CRAMPS (bilateral)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:50:47
User opened query 'Per DM CLR: Please review if the specific affected location of leg cramps can be provided (e.g. Right, Left, bilateral). Review and update Indication as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 09:36:18
User entered 'leg cramps'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '25'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'three times daily (TID)'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'un UNK 1990'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 05:10:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 05:10:48
Data point term sent to Coder	System	28 Sep 2020 20:26:26
User entered 'spironolactone'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'myocardial infarction'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '12.5'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'un UNK 2019'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 20:28:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 20:28:39
Data point term sent to Coder	System	28 Sep 2020 20:27:27
User entered 'glipizide'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'type II diabetes'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '10'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'un UNK 2014'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:30:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:30:37
User closed query 'Drug name is LOSARTAN. Please update. Thanks' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:53:01
Data point term sent to Coder	System	19 Oct 2020 20:53:44
Query 'Drug name is LOSARTAN. Please update. Thanks' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 20:53:18
User entered 'LOSARTAN' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 20:52:46
User opened query 'Drug name is LOSARTAN. Please update. Thanks' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 13:52:28
User entered 'LASARTAN' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 18:19:00
Data point term sent to Coder	System	07 Oct 2020 18:13:39
User entered 'GLIPIZIDE'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'MYOCARDIAL INFARACTION' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 18:19:00
User entered 'TYPE 2 DM'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '50' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 18:19:00
User entered '10'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'UN UNK 1989' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 18:19:00
User entered 'UN UNK 2019'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 18:19:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 18:19:00
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
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)	08 Oct 2020 06:05:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 06:05:25
Data point term sent to Coder	System	07 Oct 2020 18:15:44
User entered 'LASIX'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'MYCARDIAL INFARCTION'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '20'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'UN UNK 1989'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 18:24:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 18:24:57
Data point term sent to Coder	System	07 Oct 2020 18:17:51
User entered 'METFORMIN'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'TYPE 2 DM'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '500'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'un UNK 2014'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:24:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:24:59
Data point term sent to Coder	System	07 Oct 2020 18:21:00
User entered 'PLAVIX'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'FRONTAL LOBE STROKE'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '75'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '11 Sep 2020'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 18:24:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	07 Oct 2020 18:24:59
Data point term sent to Coder	System	07 Oct 2020 18:23:03
User entered 'INFLUENZA VACCINE'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'INFLUENZA PROPHYLAXIS'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '1'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'INJECTION'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'IM'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '04 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '04 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 17:58:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 17:58:33
Data point term sent to Coder	System	04 Nov 2020 17:42:46
User entered 'LOSARTAN'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'myocardial infarction'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '25'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '11 Sep 2020'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

[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) (b) (4)	04 Nov 2020 19:43:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 19:43:36
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
Data point term sent to Coder	System	04 Nov 2020 17:44:50
User entered 'aspirin'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'frontal lobe stroke'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '325'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'once (ONCE)'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '10 Sep 2020'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '10 Sep 2020'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:10:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:10:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:55:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:55:11
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
Data point term sent to Coder	System	04 Nov 2020 17:45:51
User entered 'diphenhydramine'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'sleep apnea'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '50'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'as needed (PRN)'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '10 Sep 2020'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

[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: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 04:57:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 04:57:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
Data point term sent to Coder	System	04 Nov 2020 17:46:52
User entered 'pravastatin'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'frontal lobe stroke'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '80'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'un Apr 2020'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 17:47:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	04 Nov 2020 17:47:25
Data point term sent to Coder	System	04 Nov 2020 17:46:52
User entered 'metformin'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'type 2 diabetes'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '500'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'twice daily (BID)'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'un Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:10:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 17:46:46

US3672278

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:10:47

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:55:00
User entered '28 Sep 2020'	(b) (4), (b) (6)	27 Oct 2020 23:14:01

US3672278

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:10:47

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:55:00
User entered 'SAE (specify) (SAE)'	(b) (4), (b) (6)	27 Oct 2020 23:14:01

US3672278

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:10:47

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

Audit	User	Time (GMT)
Query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) instead of AEID number' answered with 'Correction made.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 20:11:44
User entered 'AE#1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:11:37
User opened query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) instead of AEID number' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:50:29
User closed query 'Per CDM: Please record SAE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:17:27
Query 'Per CDM: Please record SAE record number instead of details ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 21:17:24
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 21:17:19
User entered 'USA-US116-2020-MRNA-1273-P301000001' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 21:17:19
User opened query 'Per CDM: Please record SAE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:37:39
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:55:00
User entered 'FRONTAL LOBE STROKE'	(b) (4), (b) (6)	27 Oct 2020 23:14:01

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'USA-US116-2020-MRNA-1273-P301000001'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:19
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:21:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:16:15
Un-reviewed for Safety.	System	02 Nov 2020 17:15:34
DataPoint Un-verified.	System	02 Nov 2020 17:15:34
User entered 'Yes (Y)'	System	02 Nov 2020 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:04
Amendment Manager: User entered 'Cynthia'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:01
Amendment Manager: User entered 'Strout'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:00
Amendment Manager: User entered '1156 Bowman Road'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:59
Amendment Manager: User entered 'Mount Pleasant' System		14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:12
User entered 'South Carolina'	(b) (4), (b) (6)	16 Nov 2020 21:09:52

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:57
Amendment Manager: User entered '29464'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:56
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:42:35
User entered 'US' (non-conformant).	System	12 Sep 2020 19:21:23

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Nov 2020 23:16:32
User entered '4'	System	02 Nov 2020 17:16:46
User entered '3'	System	28 Oct 2020 15:04:43
User entered '2'	System	23 Oct 2020 16:30:57
User entered '1'	System	12 Sep 2020 19:21:23

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'USA-US116-2020-MRNA-1273-P301000001'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:19
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:21:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:16:15
Un-reviewed for Safety.	System	02 Nov 2020 17:15:34
DataPoint Un-verified.	System	02 Nov 2020 17:15:34
User entered 'Yes (Y)'	System	02 Nov 2020 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:04
Amendment Manager: User entered 'Cynthia'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:01
Amendment Manager: User entered 'Strout'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:00
Amendment Manager: User entered '1156 Bowman Road'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:59
Amendment Manager: User entered 'Mount Pleasant' System		14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:12
User entered 'South Carolina'	(b) (4), (b) (6)	16 Nov 2020 21:09:52

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:57
Amendment Manager: User entered '29464'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:56
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:42:35
User entered 'US' (non-conformant).	System	12 Sep 2020 19:21:23

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Nov 2020 23:16:32
User entered '4'	System	02 Nov 2020 17:16:46
User entered '3'	System	28 Oct 2020 15:04:43
User entered '2'	System	23 Oct 2020 16:30:57
User entered '1'	System	12 Sep 2020 19:21:23

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:10:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:56
User entered '12/Sep/2020 15:21'	System	12 Sep 2020 19:21:23

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:10:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:59
User entered '1'	(b) (4), (b) (6)	12 Sep 2020 19:21:23

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'USA-US116-2020-MRNA-1273-P301000001'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:19
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:21:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:16:15
Un-reviewed for Safety.	System	02 Nov 2020 17:15:34
DataPoint Un-verified.	System	02 Nov 2020 17:15:34
User entered 'Yes (Y)'	System	02 Nov 2020 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:04
Amendment Manager: User entered 'Cynthia'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:01
Amendment Manager: User entered 'Strout'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:00
Amendment Manager: User entered '1156 Bowman Road'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:59
Amendment Manager: User entered 'Mount Pleasant' System		14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:12
User entered 'South Carolina'	(b) (4), (b) (6)	16 Nov 2020 21:09:52

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:57
Amendment Manager: User entered '29464'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:56
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:42:35
User entered 'US' (non-conformant).	System	12 Sep 2020 19:21:23

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Nov 2020 23:16:32
User entered '4'	System	02 Nov 2020 17:16:46
User entered '3'	System	28 Oct 2020 15:04:43
User entered '2'	System	23 Oct 2020 16:30:57
User entered '1'	System	12 Sep 2020 19:21:23

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:10:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:21:57
User entered '23/Oct/2020 16:30'	System	23 Oct 2020 16:30:57

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:10:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:21:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:33:21
User entered '1'	(b) (4), (b) (6)	23 Oct 2020 16:30:57

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'USA-US116-2020-MRNA-1273-P301000001'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:19
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:21:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:16:15
Un-reviewed for Safety.	System	02 Nov 2020 17:15:34
DataPoint Un-verified.	System	02 Nov 2020 17:15:34
User entered 'Yes (Y)'	System	02 Nov 2020 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:04
Amendment Manager: User entered 'Cynthia'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:01
Amendment Manager: User entered 'Strout'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:00
Amendment Manager: User entered '1156 Bowman Road'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:59
Amendment Manager: User entered 'Mount Pleasant' System		14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:12
User entered 'South Carolina'	(b) (4), (b) (6)	16 Nov 2020 21:09:52

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:57
Amendment Manager: User entered '29464'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:56
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:42:35
User entered 'US' (non-conformant).	System	12 Sep 2020 19:21:23

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Nov 2020 23:16:32
User entered '4'	System	02 Nov 2020 17:16:46
User entered '3'	System	28 Oct 2020 15:04:43
User entered '2'	System	23 Oct 2020 16:30:57
User entered '1'	System	12 Sep 2020 19:21:23

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:10:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:22:15
User entered '28/Oct/2020 15:04'	System	28 Oct 2020 15:04:43

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:10:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:22:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:16:15
User entered '1'	(b) (4), (b) (6)	28 Oct 2020 15:04:43

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'USA-US116-2020-MRNA-1273-P301000001'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:19
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:21:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:16:15
Un-reviewed for Safety.	System	02 Nov 2020 17:15:34
DataPoint Un-verified.	System	02 Nov 2020 17:15:34
User entered 'Yes (Y)'	System	02 Nov 2020 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:04
Amendment Manager: User entered 'Cynthia'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:01
Amendment Manager: User entered 'Strout'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:00
Amendment Manager: User entered '1156 Bowman Road'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:59
Amendment Manager: User entered 'Mount Pleasant' System		14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:12
User entered 'South Carolina'	(b) (4), (b) (6)	16 Nov 2020 21:09:52

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:57
Amendment Manager: User entered '29464'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:56
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:42:35
User entered 'US' (non-conformant).	System	12 Sep 2020 19:21:23

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Nov 2020 23:16:32
User entered '4'	System	02 Nov 2020 17:16:46
User entered '3'	System	28 Oct 2020 15:04:43
User entered '2'	System	23 Oct 2020 16:30:57
User entered '1'	System	12 Sep 2020 19:21:23

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:10:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:22:23
User entered '02/Nov/2020 17:16'	System	02 Nov 2020 17:16:46

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:10:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:22:24
User entered '1'	(b) (4), (b) (6)	02 Nov 2020 17:16:46

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'USA-US116-2020-MRNA-1273-P301000001'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:19
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:21:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:16:15
Un-reviewed for Safety.	System	02 Nov 2020 17:15:34
DataPoint Un-verified.	System	02 Nov 2020 17:15:34
User entered 'Yes (Y)'	System	02 Nov 2020 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:04
Amendment Manager: User entered 'Cynthia'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:01
Amendment Manager: User entered 'Strout'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:00
Amendment Manager: User entered '1156 Bowman Road'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:59
Amendment Manager: User entered 'Mount Pleasant' System		14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:12
User entered 'South Carolina'	(b) (4), (b) (6)	16 Nov 2020 21:09:52

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:57
Amendment Manager: User entered '29464'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:56
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:42:35
User entered 'US' (non-conformant).	System	12 Sep 2020 19:21:23

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:10:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Nov 2020 23:16:32
User entered '4'	System	02 Nov 2020 17:16:46
User entered '3'	System	28 Oct 2020 15:04:43
User entered '2'	System	23 Oct 2020 16:30:57
User entered '1'	System	12 Sep 2020 19:21:23

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:10:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:59
User entered '12/Nov/2020 18:16'	System	12 Nov 2020 23:16:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:10:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:17:16
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 23:16:32