

US3782073 (Prod: Vanderbilt University Medical Center)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:15:46

All time stamps listed in this document are displayed in GMT

US3782073

Form: Participant Creation

Generated On: 26 Nov 2020 11:15:46

[Participant ID](#)

US3782073

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

US3782073

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

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 11:15:46

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	56
Age Units	YEARS
Age (Derived)	56
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 11:15:46

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 11:15:46

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:15:46

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:46

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

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>)	07:56 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 07:56
Height (<i>xxx.x</i>)	174 cm
Weight (<i>xxx.x</i>)	67.1 kg
BMI (<i>xxx.x</i>)	22.16277 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:46

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: Childbearing Potential

Generated On: 26 Nov 2020 11:15:46

Date of assessment (*dd MMM yyyy*) 24 AUG 2020

Is the participant of childbearing potential? Yes ☒ No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	24 AUG 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

Occupational Risk

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

Specify

Location and Living Circumstances Risk (check all that apply)

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

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Folder: Screening

Form: Risk of Exposure

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:46

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 106887

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 11:15:46

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	07:56 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 07:56
Temperature (xxx.x)	98.5 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 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 11:15:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	09:19 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 09:19
Temperature (xxx.x)	98.2 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)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:46

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

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) 24 AUG 2020

What was the treatment time? (00:00-23:59) 08:46 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 08:46

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 11:15:46

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

24 AUG 2020

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

08:06 (24 HR)

Collection date and time (derived)

24 AUG 2020 08:06

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:46

Collection date (<i>dd MMM yyyy</i>)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:09	24 AUG 2020 08:09
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

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 11:15:46

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

24 AUG 2020 09:24

PC Open Date & Time

24 AUG 2020 09:06

PC Close Date & Time

24 AUG 2020 11:36

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 19:22

PC Open Date & Time

24 AUG 2020 12:31

PC Close Date & Time

25 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 21:03

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:46

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 23:35

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 00:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:46

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 20:41

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

29 AUG 2020 22:27

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 22:48

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 09:24

PC Open Date & Time

24 AUG 2020 09:06

PC Close Date & Time

24 AUG 2020 11:36

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

5

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 19:25

PC Open Date & Time

24 AUG 2020 12:31

PC Close Date & Time

25 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

DAY 2

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 21:04

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:46

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

26 AUG 2020 23:36

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:46

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

27 AUG 2020 23:59

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:46

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

28 AUG 2020 20:41

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:46

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

29 AUG 2020 22:25

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:46

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

30 AUG 2020 22:49

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 09:25
PC Open Date & Time	24 AUG 2020 09:06
PC Close Date & Time	24 AUG 2020 11:36

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 19:26
PC Open Date & Time	24 AUG 2020 12:31
PC Close Date & Time	25 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:46

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 ☒

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:46

Yes ☐	
PC Time stamp	25 AUG 2020 21:04
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:46

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 ☒

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:46

Yes ☐	
PC Time stamp	26 AUG 2020 23:36
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:46

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 ☒

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:46

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

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:46

		Yes ☐
PC Time stamp	28 AUG 2020 20:41	
PC Open Date & Time	28 AUG 2020 12:00	
PC Close Date & Time	29 AUG 2020 11:59	

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:46

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 ☒

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:46

Yes ☐	
PC Time stamp	29 AUG 2020 22:26
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:46

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 ☒

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:46

Yes ☐	
PC Time stamp	30 AUG 2020 22:50
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3782073

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782073

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782073

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

Was Contact Attempted?

Yes ☒

No ☐

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

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782073

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

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

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	08:01 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 08:01
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

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	

US3782073

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3782073

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	21 SEP 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

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 DUE TO RECENT ANGIOEDEMA
- SEE EPIP COMMUNICATIONS

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? _____

US3782073

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

08:10 (24 HR)

Collection date and time (derived)

21 SEP 2020 08:10

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:46

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:15	21 SEP 2020 08:15
Nasopharyngeal Swab 2	No		

US3782073

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782073

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782073

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

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

US3782073

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	21 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:30 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 08:30
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3782073

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

US3782073

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 OCT 2020

Collection time (00:00-23:59)

08:41 (24 HR)

Collection date and time (derived)

21 OCT 2020 08:41

US3782073

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

24 OCT 2020 00:02:15

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Date and time of submission	03 NOV 2020 08:28:28
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 NOV 2020 00:02:19
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2020 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 09:43:52
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2020 00:01

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27 DEC 2020 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2020 00:01

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03 JAN 2021 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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10 JAN 2021 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

Date and time of submission

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20 JAN 2021 00:01

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24 JAN 2021 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

Date and time of submission

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14 FEB 2021 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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21 FEB 2021 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

Date and time of submission

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14 MAR 2021 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

Date and time of submission

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21 MAR 2021 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

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01 AUG 2021 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

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26 SEP 2021 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

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02 JAN 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

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09 JAN 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

Date and time of submission

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12 JAN 2022 00:01

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16 JAN 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

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23 JAN 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

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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26 JAN 2022 00:01

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30 JAN 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

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Form: Safety Follow Up Diary

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Date and time of submission

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06 FEB 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

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13 FEB 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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):

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Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782073

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Date and time of submission

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20 FEB 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

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27 FEB 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

Date and time of submission

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02 MAR 2022 00:01

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06 MAR 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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Date and time of submission

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09 MAR 2022 00:01

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13 MAR 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

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20 MAR 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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23 MAR 2022 00:01

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27 MAR 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

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03 APR 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

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22 MAY 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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 JUN 2022 00:01

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03 JUL 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

Date and time of submission

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10 JUL 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

Date and time of submission

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21 AUG 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

Date and time of submission

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11 SEP 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

Date and time of submission

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18 SEP 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

Date and time of submission

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02 OCT 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

Date and time of submission

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05 OCT 2022 00:01

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09 OCT 2022 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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

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

US3782073

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782073

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

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

US3782073

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3782073

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:46

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 ☐

US3782073

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:15:46

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3782073

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:15:46

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

AEID	
Adverse event	ANGIODEMA
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)	28 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	304 of 1445

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

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	ANGIOEDEMA LOCATED ON ORAL MUCOSA, RIGHT HIP, AND BUTTOCK
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

AEID	
Adverse event	MALAISE
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)	28 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	28 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	306 of 1445

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

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

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:15:46

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

Yes ☒

No ☐

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

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

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

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

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

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

Name of Medication	BENADRYL
Prophylaxis	Yes ☐ No ☒
Indication	ANGIOEDEMA
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 ☐

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

	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)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	28 AUG 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

Name of Medication	FAMOTIDINE
Prophylaxis	Yes ☐ No ☒
Indication	ANGIOEDEMA
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 ☐

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

	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)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		28 AUG 2020
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

Name of Medication	NAPROXEN
Prophylaxis	Yes ☐ No ☒
Indication	ANGIOEDEMA
Dose per administration	220
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 ☐

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

	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)	29 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		29 AUG 2020
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 ☒	

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

Name of Medication	NAPROXEN
Prophylaxis	Yes ☐ No ☒
Indication	MALAISE
Dose per administration	220
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 ☐

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

	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)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)	28 AUG 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 ☒	

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

Name of Medication	FAMOTIDINE
Prophylaxis	Yes ☐ No ☒
Indication	ANGIOEDEMA
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 ☐

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

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

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

Name of Medication	ALLEGRA
Prophylaxis	Yes ☐ No ☒
Indication	ANGIOEDEMA
Dose per administration	180
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 ☐

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		18 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 ☐

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ☒ No ☐
Indication	INFLUENZA PROPHYLAXIS
Dose per administration	0.5
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 ☒

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

	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)		5 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		5 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

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

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

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

US3782073

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:15:46

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3782073

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:46

Date of dosing discontinuation (dd MMM yyyy)	21 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	SEE EPIP; HISTORY OF NEW ONSET ANGIOEDEMA

US3782073

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:15:46

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 ☐

Audit

US3782073 (Prod: Vanderbilt University Medical Center)

US3782073

Form: Participant Creation

Generated On: 26 Nov 2020 11:15:46

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3782073'	RWS_ENDPOINT ENDPOINT (b) (4) 	24 Aug 2020 12:49:34

US3782073

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 12:51:21

US3782073

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	24 Aug 2020 12:49:35

US3782073

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 12:51:21

US3782073

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	24 Aug 2020 12:51:21

US3782073

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered (b) (6) 1964'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Aug 2020 12:49:36

US3782073

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:46

[Age](#)

Audit	User	Time (GMT)
User entered '56'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:46

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:46

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '56'	System	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:46

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:46

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:46

White

Audit	User	Time (GMT)
User entered '1'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:46

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:46

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:46

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:46

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:46

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:46

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:46

Unknown

Audit	User	Time (GMT)
User entered '0'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:46

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '2020'	System	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:46

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:46

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:46

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:46

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Aug 2020 12:49:35

US3782073

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:46

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 12:55:54

US3782073

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:15:46

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:52:08

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:46

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Psoriatic conditions, PT: Psoriasis, LLT: Psoriasis of scalp - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 13:53:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 13:53:35
Data point term sent to Coder	System	24 Aug 2020 13:53:16
User entered 'scalp psoriasis'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'un UNK 1995'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '1995'	System	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '07:56'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 07:56'	System	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '174' cm	Carlton Griffin (b) (4)	24 Aug 2020 13:04:46
DataPoint set to visible.	(b) (4) System	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '67.1' kg	Carlton Griffin (b) (4)	24 Aug 2020 13:04:46
DataPoint set to visible.	(b) (4) System	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '22.16277'	System	17 Sep 2020 00:20:46
User entered '22.2'	System	24 Aug 2020 13:04:46
DataPoint set to visible.	System	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	24 Aug 2020 13:04:46
DataPoint set to visible.	System	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:02:57

US3782073

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:02:57

US3782073

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:35

US3782073

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:35

US3782073

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:46

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:35

US3782073

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:35

US3782073

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:35

US3782073

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:46

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:35

US3782073

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:35

US3782073

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:46

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:35

US3782073

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:52

US3782073

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:52

US3782073

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:52

US3782073

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:52

US3782073

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:52

US3782073

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:52

US3782073

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:52

US3782073

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 13:53:52

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '0'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '0'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '0'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '0'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '1'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

Other

Audit	User	Time (GMT)
User entered '0'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:46

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 12:56:06

US3782073

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 12:56:06

US3782073

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 12:56:06

US3782073

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	24 Aug 2020 12:56:06

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	24 Aug 2020 13:19:45

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '106887'	RWS_ENDPOINT ENDPOINT (b) (4) 	24 Aug 2020 13:19:45

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Aug 2020 13:19:45

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:15:54

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:15:54

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:15:54

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:15:54

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:46

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:15:54

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	Carlton Griffin (b) (4)	25 Sep 2020 18:18:08
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 10:39:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:24:44

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:46

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:46

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:46

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:46

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '07:56'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 07:56'	System	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.5' F	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '16'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '124'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '75'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:46

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:46

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '09:19'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 09:19'	System	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '16'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '132'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '84'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:21:09

US3782073

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:21:09

US3782073

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:54

US3782073

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:54

US3782073

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

[Test performed](#)

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:54

US3782073

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

[Result](#)

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:54

US3782073

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User closed query 'per CDM: please select yes or no for this field' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:15:56
Query 'per CDM: please select yes or no for this field' answered with 'updated ' (Site from DM).	Carlton Griffin (b) (4)	04 Nov 2020 19:29:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 19:29:27
User opened query 'per CDM: please select yes or no for this field' (Site from DM).	Carlton Griffin (b) (4)	04 Nov 2020 19:24:26
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:24:26
	Amber Massey (b) (4)	24 Aug 2020 13:55:54
	(b) (4)	

US3782073

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:54

US3782073

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:54

US3782073

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 13:55:54

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '08:46'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 08:46'	System	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:21:30

US3782073

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:21:30

US3782073

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '08:06'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:21:30

US3782073

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 08:06'	System	24 Aug 2020 13:21:30

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:21:51

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:46

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Carlton Griffin (b) (4)	24 Aug 2020 13:21:51

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:21:51

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:46

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '08:09'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:21:51

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 08:09'	System	24 Aug 2020 13:21:51

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:46

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Carlton Griffin (b) (4)	24 Aug 2020 13:21:51

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:21:51

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:46

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:21:51

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 13:21:51

US3782073

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:21:14

US3782073

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 13:21:14

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:23:42', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '3824708b-003b-4ec8-b5de-91a1e56477b3'	System	24 Aug 2020 14:24:04
User entered 'Yes (Y)'	System	24 Aug 2020 14:24:04

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:23:51', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '3824708b-003b-4ec8-b5de-91a1e56477b3'	System	24 Aug 2020 14:24:04
User entered '98.2'	System	24 Aug 2020 14:24:04

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:23:56', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '3824708b-003b-4ec8-b5de-91a1e56477b3'	System	24 Aug 2020 14:24:04
User entered 'No (N)'	System	24 Aug 2020 14:24:04

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:24:02', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '3824708b-003b-4ec8-b5de-91a1e56477b3'	System	24 Aug 2020 14:24:04
User entered '24 Aug 2020 09:24'	System	24 Aug 2020 14:24:04

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 09:06'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:36'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:22:22', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '23f6220a-f26f-4749-b780-693a1efe8821'	System	25 Aug 2020 00:22:41
User entered 'Yes (Y)'	System	25 Aug 2020 00:22:41

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:22:28', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '23f6220a-f26f-4749-b780-693a1efe8821'	System	25 Aug 2020 00:22:41
User entered '97.5'	System	25 Aug 2020 00:22:41

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:22:34', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '23f6220a-f26f-4749-b780-693a1efe8821'	System	25 Aug 2020 00:22:41
User entered 'No (N)'	System	25 Aug 2020 00:22:41

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:22:39', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '23f6220a-f26f-4749-b780-693a1efe8821'	System	25 Aug 2020 00:22:41
User entered '24 Aug 2020 19:22'	System	25 Aug 2020 00:22:41

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:31'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 2'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:03:29', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '4be7c488-5552-4380-ac93-f1fc53f17f27'	System	26 Aug 2020 02:03:43
User entered 'Yes (Y)'	System	26 Aug 2020 02:03:43

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:03:33', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '4be7c488-5552-4380-ac93-f1fc53f17f27'	System	26 Aug 2020 02:03:43
User entered '97.4'	System	26 Aug 2020 02:03:43

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:03:37', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '4be7c488-5552-4380-ac93-f1fc53f17f27'	System	26 Aug 2020 02:03:43
User entered 'No (N)'	System	26 Aug 2020 02:03:43

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:03:40', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '4be7c488-5552-4380-ac93-f1fc53f17f27'	System	26 Aug 2020 02:03:43
User entered '25 Aug 2020 21:03'	System	26 Aug 2020 02:03:43

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 3'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:34:58', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'f27c54e8-0099-4c28-8cbe-71335dc17f40'	System	27 Aug 2020 04:35:24
User entered 'Yes (Y)'	System	27 Aug 2020 04:35:24

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:35:14', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'f27c54e8-0099-4c28-8cbe-71335dc17f40'	System	27 Aug 2020 04:35:24
User entered '96.8'	System	27 Aug 2020 04:35:24

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:35:19', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'f27c54e8-0099-4c28-8cbe-71335dc17f40'	System	27 Aug 2020 04:35:24
User entered 'No (N)'	System	27 Aug 2020 04:35:24

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:35:21', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'f27c54e8-0099-4c28-8cbe-71335dc17f40'	System	27 Aug 2020 04:35:24
User entered '26 Aug 2020 23:35'	System	27 Aug 2020 04:35:24

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 4'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:45', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '4b54dbdd-7d85-4d1b-92fd-2752c2bb6f62'	System	28 Aug 2020 05:00:59
User entered 'Yes (Y)'	System	28 Aug 2020 05:00:59

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:50', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '4b54dbdd-7d85-4d1b-92fd-2752c2bb6f62'	System	28 Aug 2020 05:00:59
User entered '97.9'	System	28 Aug 2020 05:00:59

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:54', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '4b54dbdd-7d85-4d1b-92fd-2752c2bb6f62'	System	28 Aug 2020 05:00:59
User entered 'No (N)'	System	28 Aug 2020 05:00:59

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:57', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '4b54dbdd-7d85-4d1b-92fd-2752c2bb6f62'	System	28 Aug 2020 05:00:59
User entered '28 Aug 2020 00:00'	System	28 Aug 2020 05:00:59

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 5'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:40:48', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '2b85e4e8-973f-4db3-89ec-2fccda98c5c7'	System	29 Aug 2020 01:41:15
User entered 'Yes (Y)'	System	29 Aug 2020 01:41:15

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:40:58', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '2b85e4e8-973f-4db3-89ec-2fccda98c5c7'	System	29 Aug 2020 01:41:15
User entered '97.0'	System	29 Aug 2020 01:41:15

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:08', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '2b85e4e8-973f-4db3-89ec-2fccda98c5c7'	System	29 Aug 2020 01:41:15
User entered 'No (N)'	System	29 Aug 2020 01:41:15

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:12', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '2b85e4e8-973f-4db3-89ec-2fccda98c5c7'	System	29 Aug 2020 01:41:15
User entered '28 Aug 2020 20:41'	System	29 Aug 2020 01:41:15

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 6'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:26:34', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '835d4735-656a-4033-9966-717dbaa676f4'	System	30 Aug 2020 03:27:21
User entered 'Yes (Y)'	System	30 Aug 2020 03:27:21

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:26:38', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '835d4735-656a-4033-9966-717dbaa676f4'	System	30 Aug 2020 03:27:21
User entered '97.5'	System	30 Aug 2020 03:27:21

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:26:59', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '835d4735-656a-4033-9966-717dbaa676f4'	System	30 Aug 2020 03:27:21
User entered 'Yes (Y)'	System	30 Aug 2020 03:27:21

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed and documented' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 15:14:08
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:27:13', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '835d4735-656a-4033-9966-717dbaa676f4'	System	30 Aug 2020 03:27:21
User entered '1'	System	30 Aug 2020 03:27:21

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:27:13', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '835d4735-656a-4033-9966-717dbaa676f4'	System	30 Aug 2020 03:27:21
User entered '0'	System	30 Aug 2020 03:27:21

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:27:18', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '835d4735-656a-4033-9966-717dbaa676f4'	System	30 Aug 2020 03:27:21
User entered '29 Aug 2020 22:27'	System	30 Aug 2020 03:27:21

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 7'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:48:30', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9abbae47-acc6-41ed-b2f2-967ec0986753'	System	31 Aug 2020 03:48:44
User entered 'Yes (Y)'	System	31 Aug 2020 03:48:44

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:48:35', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9abbae47-acc6-41ed-b2f2-967ec0986753'	System	31 Aug 2020 03:48:44
User entered '98.6'	System	31 Aug 2020 03:48:44

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:48:37', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9abbae47-acc6-41ed-b2f2-967ec0986753'	System	31 Aug 2020 03:48:44
User entered 'No (N)'	System	31 Aug 2020 03:48:44

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:48:42', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9abbae47-acc6-41ed-b2f2-967ec0986753'	System	31 Aug 2020 03:48:44
User entered '30 Aug 2020 22:48'	System	31 Aug 2020 03:48:44

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:24:18', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'a9f22876-e725-4909-94e4-c5569db0b820'	System	24 Aug 2020 14:24:47
User entered 'None (1)'	System	24 Aug 2020 14:24:47

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:24:23', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'a9f22876-e725-4909-94e4-c5569db0b820'	System	24 Aug 2020 14:24:47
User entered 'No (N)'	System	24 Aug 2020 14:24:47

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:24:28', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'a9f22876-e725-4909-94e4-c5569db0b820'	System	24 Aug 2020 14:24:47
User entered 'No (N)'	System	24 Aug 2020 14:24:47

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:24:38', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'a9f22876-e725-4909-94e4-c5569db0b820'	System	24 Aug 2020 14:24:47
User entered 'None (1)'	System	24 Aug 2020 14:24:47

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:24:44', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'a9f22876-e725-4909-94e4-c5569db0b820'	System	24 Aug 2020 14:24:47
User entered '24 Aug 2020 09:24'	System	24 Aug 2020 14:24:47

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 09:06'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:36'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:22:58', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'abcd6eb-ffb0-433e-a235-197633652953'	System	25 Aug 2020 00:25:36
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 00:25:36

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:23:02', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'abcad6eb-ffb0-433e-a235-197633652953'	System	25 Aug 2020 00:25:36
User entered 'No (N)'	System	25 Aug 2020 00:25:36

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:23:07', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'abcad6eb-ffb0-433e-a235-197633652953'	System	25 Aug 2020 00:25:36
User entered 'Yes (Y)'	System	25 Aug 2020 00:25:36

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:25:14', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'abcd6eb-ffb0-433e-a235-197633652953' User entered '5'	System	25 Aug 2020 00:25:36

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:25:27', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'abcd6eb-ffb0-433e-a235-197633652953'	System	25 Aug 2020 00:25:36
User entered 'None (1)'	System	25 Aug 2020 00:25:36

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:25:34', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'abcad6eb-ffb0-433e-a235-197633652953'	System	25 Aug 2020 00:25:36
User entered '24 Aug 2020 19:25'	System	25 Aug 2020 00:25:36

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:31'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 2'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:46

[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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:03:46', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '941b796b-f9cb-437a-88db-3d36b124365e'	System	26 Aug 2020 02:04:19
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 02:04:19

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:03:49', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '941b796b-f9cb-437a-88db-3d36b124365e'	System	26 Aug 2020 02:04:19
User entered 'No (N)'	System	26 Aug 2020 02:04:19

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:02', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '941b796b-f9cb-437a-88db-3d36b124365e'	System	26 Aug 2020 02:04:19
User entered 'No (N)'	System	26 Aug 2020 02:04:19

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:08', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '941b796b-f9cb-437a-88db-3d36b124365e'	System	26 Aug 2020 02:04:19
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 02:04:19

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:13', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '941b796b-f9cb-437a-88db-3d36b124365e'	System	26 Aug 2020 02:04:19
User entered '25 Aug 2020 21:04'	System	26 Aug 2020 02:04:19

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 3'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:35:32', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd26e7c6f-ec53-427f-a1d5-ce02818a8308'	System	27 Aug 2020 04:36:24
User entered 'None (1)'	System	27 Aug 2020 04:36:24

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:35:35', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd26e7c6f-ec53-427f-a1d5-ce02818a8308'	System	27 Aug 2020 04:36:24
User entered 'No (N)'	System	27 Aug 2020 04:36:24

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:35:38', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd26e7c6f-ec53-427f-a1d5-ce02818a8308'	System	27 Aug 2020 04:36:24
User entered 'No (N)'	System	27 Aug 2020 04:36:24

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:18', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd26e7c6f-ec53-427f-a1d5-ce02818a8308'	System	27 Aug 2020 04:36:24
User entered 'None (1)'	System	27 Aug 2020 04:36:24

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:21', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd26e7c6f-ec53-427f-a1d5-ce02818a8308'	System	27 Aug 2020 04:36:24
User entered '26 Aug 2020 23:36'	System	27 Aug 2020 04:36:24

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 4'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-27T23:59:44', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '29d8a3d6-d699-418e-b306-4a18540ebe5f'	System	28 Aug 2020 05:00:05
User entered 'None (1)'	System	28 Aug 2020 05:00:05

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-27T23:59:47', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '29d8a3d6-d699-418e-b306-4a18540ebe5f'	System	28 Aug 2020 05:00:05
User entered 'No (N)'	System	28 Aug 2020 05:00:05

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-27T23:59:50', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '29d8a3d6-d699-418e-b306-4a18540ebe5f'	System	28 Aug 2020 05:00:05
User entered 'No (N)'	System	28 Aug 2020 05:00:05

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-27T23:59:54', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '29d8a3d6-d699-418e-b306-4a18540ebe5f'	System	28 Aug 2020 05:00:05
User entered 'None (1)'	System	28 Aug 2020 05:00:05

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-27T23:59:58', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '29d8a3d6-d699-418e-b306-4a18540ebe5f' User entered '27 Aug 2020 23:59'	System	28 Aug 2020 05:00:05
	System	28 Aug 2020 05:00:05

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 5'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:46

[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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:15', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '17fb1143-7c06-457b-9b26-19cae8dad8a0'	System	29 Aug 2020 01:41:33
User entered 'None (1)'	System	29 Aug 2020 01:41:33

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:19', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '17fb1143-7c06-457b-9b26-19cae8dad8a0'	System	29 Aug 2020 01:41:33
User entered 'No (N)'	System	29 Aug 2020 01:41:33

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:22', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '17fb1143-7c06-457b-9b26-19cae8dad8a0'	System	29 Aug 2020 01:41:33
User entered 'No (N)'	System	29 Aug 2020 01:41:33

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:29', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '17fb1143-7c06-457b-9b26-19cae8dad8a0'	System	29 Aug 2020 01:41:33
User entered 'None (1)'	System	29 Aug 2020 01:41:33

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:31', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '17fb1143-7c06-457b-9b26-19cae8dad8a0'	System	29 Aug 2020 01:41:33
User entered '28 Aug 2020 20:41'	System	29 Aug 2020 01:41:33

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 6'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:25:27', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'fdfcbe7f-eca3-4902-834b-e3220b135012'	System	30 Aug 2020 03:25:45
User entered 'None (1)'	System	30 Aug 2020 03:25:45

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:25:30', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'fdfcbe7f-eca3-4902-834b-e3220b135012'	System	30 Aug 2020 03:25:45
User entered 'No (N)'	System	30 Aug 2020 03:25:45

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:25:33', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'fdfcbe7f-eca3-4902-834b-e3220b135012'	System	30 Aug 2020 03:25:45
User entered 'No (N)'	System	30 Aug 2020 03:25:45

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:25:40', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'fdfcbe7f-eca3-4902-834b-e3220b135012'	System	30 Aug 2020 03:25:45
User entered 'None (1)'	System	30 Aug 2020 03:25:45

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:25:43', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'fdfcbe7f-eca3-4902-834b-e3220b135012'	System	30 Aug 2020 03:25:45
User entered '29 Aug 2020 22:25'	System	30 Aug 2020 03:25:45

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 7'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:48:46', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9919d471-7c8a-4925-aa2c-adcf30986273'	System	31 Aug 2020 03:49:09
User entered 'None (1)'	System	31 Aug 2020 03:49:09

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:48:49', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9919d471-7c8a-4925-aa2c-adcf30986273'	System	31 Aug 2020 03:49:09
User entered 'No (N)'	System	31 Aug 2020 03:49:09

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:48:52', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9919d471-7c8a-4925-aa2c-adcf30986273'	System	31 Aug 2020 03:49:09
User entered 'No (N)'	System	31 Aug 2020 03:49:09

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:48:58', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9919d471-7c8a-4925-aa2c-adcf30986273'	System	31 Aug 2020 03:49:09
User entered 'None (1)'	System	31 Aug 2020 03:49:09

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:49:07', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9919d471-7c8a-4925-aa2c-adcf30986273'	System	31 Aug 2020 03:49:09
User entered '30 Aug 2020 22:49'	System	31 Aug 2020 03:49:09

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:24:53', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9e051fe8-8afc-400c-a0e9-afecdc593d9a'	System	24 Aug 2020 14:25:28
User entered 'None (0)'	System	24 Aug 2020 14:25:28

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:25:00', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9e051fe8-8afc-400c-a0e9-afecdc593d9a'	System	24 Aug 2020 14:25:28
User entered 'None (0)'	System	24 Aug 2020 14:25:28

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:25:03', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9e051fe8-8afc-400c-a0e9-afecdc593d9a'	System	24 Aug 2020 14:25:28
User entered 'None (0)'	System	24 Aug 2020 14:25:28

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:25:07', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9e051fe8-8afc-400c-a0e9-afecdc593d9a'	System	24 Aug 2020 14:25:28
User entered 'None (0)'	System	24 Aug 2020 14:25:28

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:25:09', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9e051fe8-8afc-400c-a0e9-afecdc593d9a'	System	24 Aug 2020 14:25:28
User entered 'None (0)'	System	24 Aug 2020 14:25:28

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:25:11', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9e051fe8-8afc-400c-a0e9-afecdc593d9a'	System	24 Aug 2020 14:25:28
User entered 'None (0)'	System	24 Aug 2020 14:25:28

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:25:16', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9e051fe8-8afc-400c-a0e9-afecdc593d9a'	System	24 Aug 2020 14:25:28
User entered 'No (N)'	System	24 Aug 2020 14:25:28

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:25:24', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9e051fe8-8afc-400c-a0e9-afecdc593d9a'	System	24 Aug 2020 14:25:28
User entered '24 Aug 2020 09:25'	System	24 Aug 2020 14:25:28

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 09:06'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:36'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:26:09', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '20c45288-fb6c-4a7b-9ff7-9a44596339ec'	System	25 Aug 2020 00:26:47
User entered 'None (0)'	System	25 Aug 2020 00:26:47

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:26:14', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '20c45288-fb6c-4a7b-9ff7-9a44596339ec'	System	25 Aug 2020 00:26:47
User entered 'None (0)'	System	25 Aug 2020 00:26:47

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:26:22', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '20c45288-fb6c-4a7b-9ff7-9a44596339ec'	System	25 Aug 2020 00:26:47
User entered 'None (0)'	System	25 Aug 2020 00:26:47

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:26:29', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '20c45288-fb6c-4a7b-9ff7-9a44596339ec'	System	25 Aug 2020 00:26:47
User entered 'None (0)'	System	25 Aug 2020 00:26:47

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:26:31', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '20c45288-fb6c-4a7b-9ff7-9a44596339ec'	System	25 Aug 2020 00:26:47
User entered 'None (0)'	System	25 Aug 2020 00:26:47

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:26:33', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '20c45288-fb6c-4a7b-9ff7-9a44596339ec'	System	25 Aug 2020 00:26:47
User entered 'None (0)'	System	25 Aug 2020 00:26:47

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:26:41', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '20c45288-fb6c-4a7b-9ff7-9a44596339ec'	System	25 Aug 2020 00:26:47
User entered 'No (N)'	System	25 Aug 2020 00:26:47

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:26:45', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '20c45288-fb6c-4a7b-9ff7-9a44596339ec'	System	25 Aug 2020 00:26:47
User entered '24 Aug 2020 19:26'	System	25 Aug 2020 00:26:47

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:31'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 2'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:20', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd85cdd69-69ff-460a-ae91-4ecd1885b20a'	System	26 Aug 2020 02:04:53
User entered 'No interference with activity (1)'	System	26 Aug 2020 02:04:53

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:26', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd85cdd69-69ff-460a-ae91-4ecd1885b20a'	System	26 Aug 2020 02:04:53
User entered 'None (0)'	System	26 Aug 2020 02:04:53

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:28', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd85cdd69-69ff-460a-ae91-4ecd1885b20a'	System	26 Aug 2020 02:04:53
User entered 'None (0)'	System	26 Aug 2020 02:04:53

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:30', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd85cdd69-69ff-460a-ae91-4ecd1885b20a'	System	26 Aug 2020 02:04:53
User entered 'None (0)'	System	26 Aug 2020 02:04:53

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:32', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd85cdd69-69ff-460a-ae91-4ecd1885b20a'	System	26 Aug 2020 02:04:53
User entered 'None (0)'	System	26 Aug 2020 02:04:53

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:34', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd85cdd69-69ff-460a-ae91-4ecd1885b20a'	System	26 Aug 2020 02:04:53
User entered 'None (0)'	System	26 Aug 2020 02:04:53

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:41', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd85cdd69-69ff-460a-ae91-4ecd1885b20a'	System	26 Aug 2020 02:04:53
User entered 'No (N)'	System	26 Aug 2020 02:04:53

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:45', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd85cdd69-69ff-460a-ae91-4ecd1885b20a'	System	26 Aug 2020 02:04:53
User entered '25 Aug 2020 21:04'	System	26 Aug 2020 02:04:53

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 3'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:27', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '93cef052-9cb9-4236-980b-8a35072f564f'	System	27 Aug 2020 04:36:57
User entered 'No interference with activity (1)'	System	27 Aug 2020 04:36:57

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:30', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '93cef052-9cb9-4236-980b-8a35072f564f'	System	27 Aug 2020 04:36:57
User entered 'No interference with activity (1)'	System	27 Aug 2020 04:36:57

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:40', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '93cef052-9cb9-4236-980b-8a35072f564f'	System	27 Aug 2020 04:36:57
User entered 'None (0)'	System	27 Aug 2020 04:36:57

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:43', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '93cef052-9cb9-4236-980b-8a35072f564f'	System	27 Aug 2020 04:36:57
User entered 'No interference with activity (1)'	System	27 Aug 2020 04:36:57

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:46', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '93cef052-9cb9-4236-980b-8a35072f564f'	System	27 Aug 2020 04:36:57
User entered 'None (0)'	System	27 Aug 2020 04:36:57

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:49', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '93cef052-9cb9-4236-980b-8a35072f564f'	System	27 Aug 2020 04:36:57
User entered 'None (0)'	System	27 Aug 2020 04:36:57

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:52', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '93cef052-9cb9-4236-980b-8a35072f564f'	System	27 Aug 2020 04:36:57
User entered 'No (N)'	System	27 Aug 2020 04:36:57

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:55', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '93cef052-9cb9-4236-980b-8a35072f564f'	System	27 Aug 2020 04:36:57
User entered '26 Aug 2020 23:36'	System	27 Aug 2020 04:36:57

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 4'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:03', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'bd0dbf80-084a-4f18-9a93-592921abf513'	System	28 Aug 2020 05:00:35
User entered 'None (0)'	System	28 Aug 2020 05:00:35

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:29', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'bd0dbf80-084a-4f18-9a93-592921abf513'	System	28 Aug 2020 05:00:35
User entered 'None (0)'	System	28 Aug 2020 05:00:35

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:11', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'bd0dbf80-084a-4f18-9a93-592921abf513'	System	28 Aug 2020 05:00:35
User entered 'None (0)'	System	28 Aug 2020 05:00:35

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:16', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'bd0dbf80-084a-4f18-9a93-592921abf513'	System	28 Aug 2020 05:00:35
User entered 'None (0)'	System	28 Aug 2020 05:00:35

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:18', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'bd0dbf80-084a-4f18-9a93-592921abf513'	System	28 Aug 2020 05:00:35
User entered 'None (0)'	System	28 Aug 2020 05:00:35

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:22', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'bd0dbf80-084a-4f18-9a93-592921abf513'	System	28 Aug 2020 05:00:35
User entered 'None (0)'	System	28 Aug 2020 05:00:35

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:26', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'bd0dbf80-084a-4f18-9a93-592921abf513'	System	28 Aug 2020 05:00:35
User entered 'No (N)'	System	28 Aug 2020 05:00:35

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:32', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'bd0dbf80-084a-4f18-9a93-592921abf513'	System	28 Aug 2020 05:00:35
User entered '28 Aug 2020 00:00'	System	28 Aug 2020 05:00:35

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 5'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:37', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6a5d8a16-6421-4427-aa78-363e3c0c25ff'	System	29 Aug 2020 01:42:01
User entered 'None (0)'	System	29 Aug 2020 01:42:01

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:40', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6a5d8a16-6421-4427-aa78-363e3c0c25ff'	System	29 Aug 2020 01:42:01
User entered 'None (0)'	System	29 Aug 2020 01:42:01

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:43', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6a5d8a16-6421-4427-aa78-363e3c0c25ff'	System	29 Aug 2020 01:42:01
User entered 'None (0)'	System	29 Aug 2020 01:42:01

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:45', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6a5d8a16-6421-4427-aa78-363e3c0c25ff'	System	29 Aug 2020 01:42:01
User entered 'None (0)'	System	29 Aug 2020 01:42:01

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:47', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6a5d8a16-6421-4427-aa78-363e3c0c25ff'	System	29 Aug 2020 01:42:01
User entered 'None (0)'	System	29 Aug 2020 01:42:01

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:49', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6a5d8a16-6421-4427-aa78-363e3c0c25ff'	System	29 Aug 2020 01:42:01
User entered 'None (0)'	System	29 Aug 2020 01:42:01

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:57', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6a5d8a16-6421-4427-aa78-363e3c0c25ff' User entered 'Yes (Y)'	System	29 Aug 2020 01:42:01
	System	29 Aug 2020 01:42:01

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:59', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6a5d8a16-6421-4427-aa78-363e3c0c25ff' User entered '28 Aug 2020 20:41'	System	29 Aug 2020 01:42:01
	System	29 Aug 2020 01:42:01

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 6'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:25:57', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ba88fe17-acec-4d1b-9fba-d6a8196105ee' User entered 'None (0)'	System	30 Aug 2020 03:26:31

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:25:59', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ba88fe17-acec-4d1b-9fba-d6a8196105ee' User entered 'None (0)'	System	30 Aug 2020 03:26:31
	System	30 Aug 2020 03:26:31

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:26:02', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ba88fe17-acec-4d1b-9fba-d6a8196105ee'	System	30 Aug 2020 03:26:31
User entered 'None (0)'	System	30 Aug 2020 03:26:31

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:26:05', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ba88fe17-acec-4d1b-9fba-d6a8196105ee'	System	30 Aug 2020 03:26:31
User entered 'None (0)'	System	30 Aug 2020 03:26:31

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:26:08', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ba88fe17-acec-4d1b-9fba-d6a8196105ee'	System	30 Aug 2020 03:26:31
User entered 'None (0)'	System	30 Aug 2020 03:26:31

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:26:10', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ba88fe17-acec-4d1b-9fba-d6a8196105ee' User entered 'None (0)'	System	30 Aug 2020 03:26:31

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:26:27', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ba88fe17-acec-4d1b-9fba-d6a8196105ee'	System	30 Aug 2020 03:26:31
User entered 'No (N)'	System	30 Aug 2020 03:26:31

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:26:29', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ba88fe17-acec-4d1b-9fba-d6a8196105ee'	System	30 Aug 2020 03:26:31
User entered '29 Aug 2020 22:26'	System	30 Aug 2020 03:26:31

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 7'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:49:11', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e802c222-89fa-4367-b160-0128f05a7b34'	System	31 Aug 2020 03:50:26
User entered 'None (0)'	System	31 Aug 2020 03:50:26

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:49:16', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e802c222-89fa-4367-b160-0128f05a7b34'	System	31 Aug 2020 03:50:26
User entered 'None (0)'	System	31 Aug 2020 03:50:26

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:49:18', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e802c222-89fa-4367-b160-0128f05a7b34'	System	31 Aug 2020 03:50:26
User entered 'None (0)'	System	31 Aug 2020 03:50:26

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:49:20', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e802c222-89fa-4367-b160-0128f05a7b34'	System	31 Aug 2020 03:50:26
User entered 'None (0)'	System	31 Aug 2020 03:50:26

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:49:54', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e802c222-89fa-4367-b160-0128f05a7b34'	System	31 Aug 2020 03:50:26
User entered 'None (0)'	System	31 Aug 2020 03:50:26

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:50:00', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e802c222-89fa-4367-b160-0128f05a7b34'	System	31 Aug 2020 03:50:26
User entered 'None (0)'	System	31 Aug 2020 03:50:26

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:50:09', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e802c222-89fa-4367-b160-0128f05a7b34'	System	31 Aug 2020 03:50:26
User entered 'No (N)'	System	31 Aug 2020 03:50:26

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:50:24', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e802c222-89fa-4367-b160-0128f05a7b34'	System	31 Aug 2020 03:50:26
User entered '30 Aug 2020 22:50'	System	31 Aug 2020 03:50:26

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 14:06:16

US3782073

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 14:06:16

US3782073

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	31 Aug 2020 14:06:16

US3782073

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 14:06:16

US3782073

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 14:06:22

US3782073

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 14:06:22

US3782073

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:57:00

US3782073

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '7 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 16:57:00

US3782073

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Sep 2020 16:57:00

US3782073

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:57:00

US3782073

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:57:08

US3782073

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 16:57:08

US3782073

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	14 Sep 2020 13:04:25

US3782073

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Carlton Griffin (b) (4) (b) (4)	14 Sep 2020 13:04:25

US3782073

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4) (b) (4)	14 Sep 2020 13:04:25

US3782073

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Carlton Griffin (b) (4) (b) (4)	14 Sep 2020 13:04:25

US3782073

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	14 Sep 2020 13:04:31

US3782073

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 13:04:31

US3782073

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 21:55:24

US3782073

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 21:55:24

US3782073

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Sep 2020 21:55:24

US3782073

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	21 Sep 2020 21:55:24

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '08:01'	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 08:01'	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '59'	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '124'	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '72'	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	27 Oct 2020 16:32:26
Comment added 'did not receive 2nd dose, so no post-vaccine VS done'.	(b) (4), (b) (6)	17 Oct 2020 16:07:14
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	15 Oct 2020 16:28:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty; reason for change Per Query Resolution	Carlton Griffin (b) (4) (b) (4)	27 Oct 2020 16:32:26
User closed query 'per CDM: please use drop down menu to enter ND for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP if vitals were not taken' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:04:55
Query 'per CDM: please use drop down menu to enter ND for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP if vitals were not taken' answered with 'updated- query still showing up that vital signs were not assessed but data is provided. is this correct?' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	15 Oct 2020 16:29:20
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carlton Griffin (b) (4) (b) (4)	15 Oct 2020 16:28:46
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carlton Griffin (b) (4) (b) (4)	15 Oct 2020 16:28:34
User opened query 'per CDM: please use drop down menu to enter ND for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP if vitals were not taken' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 16:12:57
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty; reason for change Per Query Resolution	Carlton Griffin (b) (4)	27 Oct 2020 16:32:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carlton Griffin (b) (4)	15 Oct 2020 16:28:34
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 16:32:26
User entered 'bpm'	System	15 Oct 2020 16:28:34
User entered empty.	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty; reason for change Per Query Resolution	Carlton Griffin (b) (4)	27 Oct 2020 16:32:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carlton Griffin (b) (4)	15 Oct 2020 16:28:34
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 16:32:26
User entered 'breaths/min'	System	15 Oct 2020 16:28:34
User entered empty.	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty; reason for change Per Query Resolution	Carlton Griffin (b) (4)	27 Oct 2020 16:32:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carlton Griffin (b) (4)	15 Oct 2020 16:28:34
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 16:32:26
User entered 'mmHg'	System	15 Oct 2020 16:28:34
User entered empty.	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty; reason for change Per Query Resolution	Carlton Griffin (b) (4)	27 Oct 2020 16:32:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carlton Griffin (b) (4)	15 Oct 2020 16:28:34
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 16:32:26
User entered 'mmHg'	System	15 Oct 2020 16:28:34
User entered empty.	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 21:58:43

US3782073

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 21:58:43

US3782073

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 22:00:34

US3782073

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 22:00:34

US3782073

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	(b) (4), (b) (6)	21 Sep 2020 22:00:34

US3782073

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	21 Sep 2020 22:00:34

US3782073

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 22:00:34

US3782073

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:00:34

US3782073

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:00:34

US3782073

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:00:34

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered 'Physician Decision (PHYSICIAN DECISION)' reason for change: New Information	(b) (4), (b) (6)	22 Sep 2020 20:38:09
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4), (b) (6)	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Due to recent angioedema - see ePip communications'	(b) (4), (b) (6)	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 21:59:46

US3782073

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 21:59:46

US3782073

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '08:10'	(b) (4), (b) (6)	21 Sep 2020 21:59:46

US3782073

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 08:10'	System	21 Sep 2020 21:59:46

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 22:00:09

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:46

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Sep 2020 22:00:09

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 22:00:09

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:46

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '08:15'	(b) (4), (b) (6)	21 Sep 2020 22:00:09

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 08:15'	System	21 Sep 2020 22:00:09

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:46

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Sep 2020 22:00:09

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 22:00:09

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:46

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:00:09

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:00:09

US3782073

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 22:13:02

US3782073

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 22:13:02

US3782073

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	29 Sep 2020 13:00:17

US3782073

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Carlton Griffin (b) (4) (b) (4)	29 Sep 2020 13:00:17

US3782073

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4) (b) (4)	29 Sep 2020 13:00:17

US3782073

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Carlton Griffin (b) (4) (b) (4)	29 Sep 2020 13:00:17

US3782073

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	29 Sep 2020 13:00:25

US3782073

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 13:00:25

US3782073

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 14:42:55

US3782073

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 14:42:55

US3782073

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 14:42:55

US3782073

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 14:42:55

US3782073

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 14:43:01

US3782073

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 14:43:01

US3782073

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:41:45

US3782073

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:41:45

US3782073

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:41:45

US3782073

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:41:45

US3782073

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:41:52

US3782073

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 16:41:52

US3782073

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:44:22

US3782073

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:44:22

US3782073

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:44:22

US3782073

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:46

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	21 Oct 2020 13:44:22

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '08:30'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 08:30'	System	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '16'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '117'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '70'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:44:12

US3782073

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:44:12

US3782073

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:46:13

US3782073

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:46:13

US3782073

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '08:41'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:46:13

US3782073

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 08:41'	System	21 Oct 2020 13:46:13

US3782073

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:44:02

US3782073

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 13:44:02

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 64'	System	24 Aug 2020 13:56:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-10-24T00:01:48', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'cf1253b3-d82c-44cd-bc75-459435347448'	System	24 Oct 2020 05:02:19
User entered 'No (N)'	System	24 Oct 2020 05:02:19

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

Have you been exposed to someone with 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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-10-24T00:02:10', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'cf1253b3-d82c-44cd-bc75-459435347448'	System	24 Oct 2020 05:02:19
User entered 'No (N)'	System	24 Oct 2020 05:02:19

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-10-24T00:02:15', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'cf1253b3-d82c-44cd-bc75-459435347448'	System	24 Oct 2020 05:02:19
User entered '24 Oct 2020 00:02:15'	System	24 Oct 2020 05:02:19

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 13:56:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 71'	System	24 Aug 2020 13:56:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-03T08:28:08', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '5fed8e05-cc4a-471f-9444-f63c2c990747'	System	03 Nov 2020 14:28:30
User entered 'Yes (Y)'	System	03 Nov 2020 14:28:30

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

Have you been exposed to someone with 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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-03T08:28:12', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '5fed8e05-cc4a-471f-9444-f63c2c990747'	System	03 Nov 2020 14:28:30
User entered 'No (N)'	System	03 Nov 2020 14:28:30

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

Have you experienced any new COVID-19 disease symptoms 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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-03T08:28:16', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '5fed8e05-cc4a-471f-9444-f63c2c990747'	System	03 Nov 2020 14:28:30
User entered 'No (N)'	System	03 Nov 2020 14:28:30

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Have you had to contact a healthcare provider 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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-03T08:28:23', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '5fed8e05-cc4a-471f-9444-f63c2c990747'	System	03 Nov 2020 14:28:30
User entered 'No (N)'	System	03 Nov 2020 14:28:30

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-03T08:28:28', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '5fed8e05-cc4a-471f-9444-f63c2c990747'	System	03 Nov 2020 14:28:30
User entered '03 Nov 2020 08:28:28'	System	03 Nov 2020 14:28:30

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 13:56:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 78'	System	24 Aug 2020 13:56:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-07T00:01:44', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6c57d70c-dc12-43d4-8a10-9faf064e3b26'	System	07 Nov 2020 06:03:20
User entered 'No (N)'	System	07 Nov 2020 06:03:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

Have you been exposed to someone with 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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-07T00:01:49', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6c57d70c-dc12-43d4-8a10-9faf064e3b26'	System	07 Nov 2020 06:03:20
User entered 'No (N)'	System	07 Nov 2020 06:03:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-07T00:02:19', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6c57d70c-dc12-43d4-8a10-9faf064e3b26'	System	07 Nov 2020 06:03:20
User entered '07 Nov 2020 00:02:19'	System	07 Nov 2020 06:03:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 13:56:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 13:56:20
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '21 Oct 2020 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '25 Oct 2020 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '28 Oct 2020 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '01 Nov 2020 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '04 Nov 2020 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '08 Nov 2020 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '11 Nov 2020 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '15 Nov 2020 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-21T09:43:37', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e7397c22-4419-48fb-8443-195789398ac5'	System	21 Nov 2020 15:43:54
User entered 'No (N)'	System	21 Nov 2020 15:43:54

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

Have you been exposed to someone with 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 (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-21T09:43:47', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e7397c22-4419-48fb-8443-195789398ac5'	System	21 Nov 2020 15:43:54
User entered 'No (N)'	System	21 Nov 2020 15:43:54

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-21T09:43:52', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e7397c22-4419-48fb-8443-195789398ac5' User entered '21 Nov 2020 09:43:52'	System	21 Nov 2020 15:43:54

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:33:36

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:33:36

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:33:36

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:33:36

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:33:36

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Folder: New Safety Follow Up Diary (1)

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Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:33:36

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:33:36

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:33:36

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:33:36

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:33:36

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:33:36

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	16 Nov 2020 15:58:40

US3782073

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Carlton Griffin (b) (4) (b) (4)	16 Nov 2020 15:58:40

US3782073

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4) (b) (4)	16 Nov 2020 15:58:40

US3782073

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Carlton Griffin (b) (4) (b) (4)	16 Nov 2020 15:58:40

US3782073

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	16 Nov 2020 15:58:47

US3782073

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 15:58:47

US3782073

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:15:46

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Aug 2020 19:04:40

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Otherwise, specify the anatomical location of ANGIOEDEMA. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 18:40:17
Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Otherwise, specify the anatomical location of ANGIOEDEMA. ' answered with 'no known underlying medical condition. see narrative below for location of angioedema ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	03 Nov 2020 14:10:20
User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Otherwise, specify the anatomical location of ANGIOEDEMA. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 06:30:15
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Angioedemas, PT: Angioedema, LLT: Angioedema - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:45:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:45:47
Data point term sent to Coder	System	21 Sep 2020 22:15:50
Coding entries removed.	(b) (4), (b) (6)	21 Sep 2020 22:15:01
User entered 'ANGIOEDEMA' reason for change: New Information	(b) (4), (b) (6)	21 Sep 2020 22:15:01
User coded data point as SOC: Gastrointestinal disorders, HLGT: Oral soft tissue conditions, HLT: Oral soft tissue swelling and oedema, PT: Mouth swelling, LLT: Oral mucosa swollen - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:43:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:43:48
Data point term sent to Coder	System	08 Sep 2020 15:23:22

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	(b) (4), (b) (6)	08 Sep 2020 15:23:07
User entered 'Angiodema localized to oral mucosa' reason for change: New Information	(b) (4), (b) (6)	08 Sep 2020 15:23:07
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Food allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 20:51:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 20:51:37
Data point term sent to Coder	System	30 Aug 2020 19:08:59
User entered 'allergic reaction - likely to food'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	26 Oct 2020 20:58:34
User entered 'No (N)'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the AE term is not one of the protocol defined Solicited AR. Please review and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:27:53
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the AE term is not one of the protocol defined Solicited AR. Please review and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Carlton Griffin (b) (4)	24 Sep 2020 18:48:32
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	24 Sep 2020 18:47:56
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the AE term is not one of the protocol defined Solicited AR. Please review and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:37:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	30 Aug 2020 19:09:07
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Aug 2020 19:09:07
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	30 Aug 2020 19:08:27
User entered '18:45'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Aug 2020 19:09:07
User entered '28 Aug 2020 18:45'	System	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	21 Sep 2020 22:15:01
User entered 'No (N)'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change New Information	(b) (4), (b) (6)	21 Sep 2020 22:15:01
User entered '30 Aug 2020'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	30 Aug 2020 19:09:20
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Aug 2020 19:09:20
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	30 Aug 2020 19:08:27
User entered '07:00'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Aug 2020 19:09:20
User entered '30 Aug 2020 07:00'	System	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:30:20
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).		21 Sep 2020 22:15:01
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 14:03:07
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'INVESTIGATIONAL PRODUCT WITHDRAWN PER PHYSICIAN DECISION' (Site from System).	Carlton Griffin (b) (4)	24 Sep 2020 18:48:23
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	23 Sep 2020 13:14:59
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	(b) (4), (b) (6)	21 Sep 2020 22:15:01
User entered 'None (NONE)'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	21 Sep 2020 22:15:01
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Aug 2020 19:09:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Aug 2020 19:09:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Aug 2020 19:09:36
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Aug 2020 19:08:27
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Narrative](#)

Audit	User	Time (GMT)
User entered 'angioedema located on oral mucosa, right hip, and buttock' reason for change: New Information	Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 15:29:44
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 20:58:34
User entered '0'	System	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Malaise, LLT: Malaise - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:25:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:25:45
Data point term sent to Coder	System	08 Sep 2020 15:24:24
User entered 'malaise'	(b) (4), (b) (6) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the AE term is not one of the protocol defined Solicited AR. Please review and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:28:12
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the AE term is not one of the protocol defined Solicited AR. Please review and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Carlton Griffin (b) (4)	24 Sep 2020 18:49:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	24 Sep 2020 18:49:13
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the AE term is not one of the protocol defined Solicited AR. Please review and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:37:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:24:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 15:24:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 15:24:33
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:24:20
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Sep 2020 15:24:20

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:15:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:57:38

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORETHISTERONE ACETATE, PRODUCTSYNONYM: MICROGESTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 18:57:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 18:57:41
Data point term sent to Coder	System	21 Oct 2020 18:56:59
Coding entries removed.	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 18:56:11
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORETHISTERONE ACETATE, PRODUCTSYNONYM: MICROGESTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:07:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:07:06
Data point term sent to Coder	System	24 Aug 2020 13:58:33
User entered 'microgestin'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please reconcile with Med History eCRF so there is an appropriate condition recorded.	(b) (4), (b) (6)	11 Nov 2020 15:49:04
' (Site from DM). Query 'Per CDM: Please reconcile with Med History eCRF so there is an appropriate condition recorded.	Carlton Griffin (b) (4) (b) (4)	29 Oct 2020 17:59:36
' answered with 'no condition associated with taking a contraceptive' (Site from DM). User opened query 'Per CDM: Please reconcile with Med History eCRF so there is an appropriate condition recorded.	(b) (4), (b) (6)	28 Oct 2020 18:24:37
' (Site from DM). User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded.	(b) (4), (b) (6)	28 Oct 2020 18:23:16
' (Site from DM). Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded.	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 18:56:21
' answered with 'updated- thanks! ' (Site from DM). User entered 'contraception' reason for change: Per Query Resolution	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 18:56:11
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded.	(b) (4), (b) (6)	21 Oct 2020 07:55:12
' (Site from DM). User entered 'oral contraceptive'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'un Oct 2010'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

[Name of Medication](#)

Audit	User	Time (GMT)
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)	12 Oct 2020 17:33:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:33:39
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: ACRIVASTINE, PRODUCTSYNONYM: BENADRYL [ACRIVASTINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 22:10:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 22:10:39
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	22 Sep 2020 14:00:47 22 Sep 2020 13:59:57
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIHISTAMINES FOR TOPICAL USE, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 23:12:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 23:12:00
Data point term sent to Coder	System	08 Sep 2020 15:26:32
v6.020 DTW (1102)		1298 of 1445

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	(b) (4), (b) (6)	08 Sep 2020 15:26:12
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)	31 Aug 2020 04:48:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 04:48:44
Data point term sent to Coder	System	30 Aug 2020 19:11:02
User entered 'Benadryl'	(b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:50:04
Query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' answered with 'see updated AE narrative for location of angioedema. AE is not solicited. ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 15:30:24
User opened query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:15:54
User entered 'ANGIOEDEMA' reason for change: New Information	(b) (4), (b) (6)	22 Sep 2020 13:59:57
User entered 'Angioedema localized to oral mucosa' reason for change: New Information	(b) (4), (b) (6)	08 Sep 2020 15:26:12
User entered 'likely food allergy'	(b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	(b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	30 Aug 2020 19:11:55
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Aug 2020 19:11:55
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	30 Aug 2020 19:10:53
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:11:45
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' answered with 'updated' (Site from DM).	Carlton Griffin (b) (4)	21 Oct 2020 14:28:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:27:48
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 14:01:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 14:01:43
Data point term sent to Coder	System	22 Sep 2020 14:00:47
Coding entries removed.	(b) (4), (b) (6)	22 Sep 2020 14:00:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 18:09:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 18:09:46
Data point term sent to Coder	System	08 Sep 2020 15:26:33
Coding entries removed.	(b) (4), (b) (6)	08 Sep 2020 15:26:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 04:53:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 04:53:55
Data point term sent to Coder	System	30 Aug 2020 19:12:04
User entered 'Famotidine'	(b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:51:08
Query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' answered with 'see updated AE narrative for location of angioedema. AE is not solicited. ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 15:31:50
User opened query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:16:21
User entered 'ANGIOEDEMA' reason for change: New Information	(b) (4), (b) (6)	22 Sep 2020 14:00:25
User entered 'Angioedema localized to oral mucosa' reason for change: New Information	(b) (4), (b) (6)	08 Sep 2020 15:26:31
User entered 'likely food allergy'	(b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	(b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	30 Aug 2020 19:11:36
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Aug 2020 19:11:36
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	30 Aug 2020 19:11:26
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:12:00
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' answered with 'updated ' (Site from DM).	Carlton Griffin (b) (4)	21 Oct 2020 14:28:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:28:29
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:55:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 14:33:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 14:33:59
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	22 Sep 2020 14:01:50 22 Sep 2020 14:00:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:49:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:49:36
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	08 Sep 2020 15:26:26 08 Sep 2020 15:25:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 05:03:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 05:03:48
Data point term sent to Coder User entered 'Naproxen'	System (b) (4), (b) (6)	30 Aug 2020 19:15:05 30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:51:19
Query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' answered with 'see updated AE narrative for location of angioedema. AE is not solicited. ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 15:31:59
User opened query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:17:23
User entered 'ANGIOEDEMA' reason for change: New Information	(b) (4), (b) (6)	22 Sep 2020 14:00:54
User entered 'Angioedema localized to oral mucosa' reason for change: New Information	(b) (4), (b) (6)	08 Sep 2020 15:25:39
User entered 'likely food allergy'	(b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '220'	(b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '29 Aug 2020'	(b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	(b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:12:13
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' answered with 'updated' (Site from DM).	Carlton Griffin (b) (4)	21 Oct 2020 14:28:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:28:49
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:55:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:09:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:09:48
Data point term sent to Coder	System	08 Sep 2020 15:28:34
User entered 'naproxen'	(b) (4), (b) (6) (b) (4)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

[Indication](#)

Audit	User	Time (GMT)
User entered 'malaise'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '220'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:12:28
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' answered with 'updated' (Site from DM).	Carlton Griffin (b) (4)	21 Oct 2020 14:29:11
User entered 'No (N)' reason for change: Data Entry Error	Carlton Griffin (b) (4)	21 Oct 2020 14:29:06
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:56:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 01:03:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 01:03:51
Data point term sent to Coder	System	21 Sep 2020 22:04:30
User entered 'famotidine'	(b) (4), (b) (6) (b) (4)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:51:31
Query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' answered with 'see updated AE narrative for location of angioedema. AE is not solicited. ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 15:32:07
User opened query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:16:53
User entered 'angioedema'	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '12 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

[Name of Medication](#)

Audit	User	Time (GMT)
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: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:05:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:05:51
Data point term sent to Coder	System	21 Sep 2020 22:05:30
User entered 'allegra'	(b) (4), (b) (6) (b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:51:43
Query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' answered with 'see updated AE narrative for location of angioedema. AE is not solicited. ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 15:32:15
User opened query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:15:30
User entered 'angioedema'	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '180'	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '18 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 16:45:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 16:45:19
Data point term sent to Coder	System	12 Oct 2020 16:44:05
User entered 'Influenza Vaccine'	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

[Indication](#)

Audit	User	Time (GMT)
User entered 'Influenza Prophylaxis'	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered '5 Oct 2020'	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '5 Oct 2020'	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Kerrigan (b) (4) (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:11:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:11:41
Data point term sent to Coder	System	21 Oct 2020 14:10:26
User entered 'multivitamin'	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:51:55
Query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'medication not prophylactic or preventative. not associated with a diagnosis. ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	30 Oct 2020 13:16:00
User opened query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 18:52:54
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

[Indication](#)

Audit	User	Time (GMT)
User entered 'general health'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Oct 2020 14:10:41
User entered 'UN UNK 2000' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 14:10:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Oct 2020 14:10:25
User entered 'un 2000' (non-conformant).	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 14:10:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 14:10:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 14:10:25

US3782073

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:46

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 13:14:59

US3782073

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:46

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	(b) (4), (b) (6)	23 Sep 2020 13:14:59

US3782073

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:46

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

Audit	User	Time (GMT)
User entered 'see ePip; history of new onset angioedema'	(b) (4), (b) (6)	23 Sep 2020 13:14:59